UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

IN RE OUTLOOK THERAPEUTICS, INC. SECURITIES LITIGATION	Case No. 2:23-cv-21862-MCA-CLW
THIS DOCUMENT RELATES TO: ALL FILINGS	**CLASS ACTION** **CONSOLIDATED AMENDED CLASS ACTION COMPLAINT** **JURY TRIAL DEMANDED**

Lead Plaintiff Jason Solomon and Additional Plaintiffs Ramzy Alsaidi, Michael Lucas, and Mariam Silverman, Trustee for the Mariam Silverman Trust UA Mar. 15, 1969 (collectively, "Plaintiffs"), individually and on behalf of all others similarly situated, by Plaintiffs' undersigned attorneys, allege the following based upon personal knowledge as to Plaintiffs and Plaintiffs' own acts, and information and belief as to all other matters, based upon, *inter alia*, the investigation conducted by and through Plaintiffs' attorneys, which included, among other things, a review of the Defendants' public documents, conference calls and announcements made by Defendants, United States ("U.S.") Securities and Exchange Commission ("SEC") filings, wire and press releases published by and regarding Outlook Therapeutics, Inc. f/k/a Oncobiologics, Inc. ("Outlook" or the "Company"), analysts' reports and advisories about the Company, and information readily obtainable on the Internet.

Plaintiffs believe that substantial, additional evidentiary support will exist for the allegations set forth herein after a reasonable opportunity for discovery.

NATURE OF THE ACTION[1]

1. This is a federal securities class action on behalf of a class consisting of all persons and entities that purchased or otherwise acquired Outlook securities between August 3, 2021 and August 29, 2023, both dates inclusive (the "Class Period"), seeking to recover damages caused by Defendants' violations of the federal securities laws and to pursue remedies under Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 ("Exchange Act") and Rule 10b-5 promulgated thereunder. Excluded from the class are Defendants, current and former officers and directors, and the immediate families of any of the above.

2. Outlook is a late clinical-stage biopharmaceutical company that focuses on developing and commercializing monoclonal antibodies for ophthalmic indications. According to the Company's Form 10-K filed on December 22, 2023, the Company maintained only twenty-four full-time employees. The Company's lead product candidate is ONS-5010, an ophthalmic formulation of the monoclonal antibody bevacizumab for treating wet age-related macular degeneration ("wet AMD") and other retina diseases.

[1] Unless otherwise noted, all emphasis is supplied.

3. Outlook began as a company focusing on creating treatments in the fields of immunology and oncology; however, the Company soon discovered that ONS-5010 could become a lucrative treatment for wet AMD. Beginning in early 2018, the Company began to quickly shift its complete focus on the development of ONS-5010 as an FDA-approved treatment for wet AMD, abandoning the development of two drug candidates, ONS-3010 and ONS-1045. Additionally, the Company changed its name to Outlook to reflect its new endeavor into the ophthalmology field and hired veterans in the field, including Defendant Trenary as CEO, to lead the development and commercialization of ONS-5010, its only clinical-stage drug candidate.

4. At all relevant times, ONS-5010 has been Outlook's flagship drug candidate, and Outlook admits that its ability to generate revenue and achieve profitability completely depends on its ability to gain regulatory and marketing approval for ONS-5010.

5. A critical hurdle to commercializing any drug is obtaining FDA approval, which assesses the evidence of the drug's efficacy and safety from clinical trials and the ability of manufacturing facilities to mass produce the drug in accordance with FDA's Current Good Manufacturing Practices regulations ("cGMP"). If the drug application fails at any one of these points, then the FDA issues a Complete Response Letter ("CRL"). Pursuant to federal regulations, a CRL

states that FDA will not approve the application in its present form, denotes all the specific deficiencies the FDA has identified in the application, and recommends all the corrective actions that a sponsor can take to rectify its mistakes.

6. Outlook purportedly submitted two Phase III clinical studies, NORSE 1 and NORSE 2, in its Biologics License Application ("BLA"), seeking FDA approval to market and commercialize ONS-5010.

7. However, NORSE 1 and NORSE 2 could never have served as sufficient bases for a BLA because they did not adhere to the FDA's requirement or the ophthalmology field's custom and practice that "safety and efficacy should be demonstrated in at least two adequate and well-controlled, multicenter trials" and that "approximately 400 or more patients using the investigational drug complete treatment."

8. Furthermore, as part of its pivot to ONS-5010, Outlook shuttered its in-house drug manufacturing and partnered with third-party drug manufacturers. However, despite assurances from the Defendants that its manufacturing partners were "best-in-class" and that each could "provide product manufacturing in current Good Manufacturing Practices," both manufacturing partners were cited for cGMP violations before and during the Class Period, with one manufacturing partner receiving notice of its manufacturing deficiencies on June 10, 2021.

9. FDA notified Defendants as early as May 2022 that there were issues with their drug manufacturing partners, but Defendants swept away those concerns and assured investors that they had "worked diligently to provide the additional required information that was not included in our March 2022 BLA submission." After the Class-Period, Defendant Trenary would admit that a number of the same issues first cited by the FDA in May 2022 were cited again in the August 30, 2023 CRL.

10. Throughout the Class Period, Defendants made materially false and misleading statements regarding the Company's business, operations, and prospects. Specifically, Defendants made false and misleading statements concealing that: (i) there was a lack of substantial evidence supporting ONS-5010 as a treatment for wet AMD; (ii) Outlook and/or its manufacturing partners maintained deficient chemistry manufacturing and controls ("CMC") and other manufacturing issues for ONS-5010, which remained unresolved at the time the ONS-5010 BLA was re-submitted to the FDA; (iii) as a result of all the foregoing, the FDA was unlikely to approve the ONS-5010 BLA in its present form; (iv) accordingly, ONS-5010's regulatory and commercial prospects were overstated; and (v) as a result, the Company's public statements were materially false and misleading at all relevant times.

11. On May 31, 2022, the Company issued a press release announcing that the FDA requested additional information regarding the Company's ONS-5010 BLA submission.

12. As a result of this partial disclosure and/or the materialization of concealed risks, the Company's stock price declined by nearly 6.96% from its previous day closing price of $1.15 on May 31, 2022 to close at $1.07 on June 1, 2022, on heavy trading volume.[2]

13. On August 30, 2023, Outlook admitted that the FDA had issued a CRL declining Outlook's ONS-5010 BLA. The Company revealed that, "the Agency concluded it could not approve the BLA during this review cycle due to several CMC issues, open observations from pre-approval manufacturing inspections, and a lack of substantial evidence."

14. On this news, Outlook's stock price fell $1.141 per share, or 80.92%, to close at $0.269 per share on August 30, 2023.

15. As a result of Defendants' wrongful acts and omissions, and the precipitous decline in the market value of the Company's securities, Plaintiffs and other Class members have suffered significant losses and damages.

[2] On March 14, 2024, Outlook underwent a one-for twenty reverse stock split of its common stock in order to meet the NASDAQ's stock price listing requirement. All references to Outlook stock prices are without adjustment for this post-Class Period reverse stock split.

JURISDICTION AND VENUE

16. The claims asserted herein arise under and pursuant to Sections 10(b) and 20(a) of the Exchange Act (15 U.S.C. §§ 78j(b) and 78t(a)) and Rule 10b-5 promulgated thereunder by the SEC (17 C.F.R. § 240.10b-5).

17. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. § 1331 and Section 27 of the Exchange Act.

18. Venue is proper in this Judicial District pursuant to Section 27 of the Exchange Act (15 U.S.C. § 78aa) and 28 U.S.C. § 1391(b). Outlook is headquartered in this Judicial District, Defendants conduct business in this Judicial District, and a significant portion of Defendants' actions took place within this Judicial District.

19. In connection with the acts alleged in this Complaint, Defendants, directly or indirectly, used the means and instrumentalities of interstate commerce, including, but not limited to, the mails, interstate telephone communications, and the facilities of the national securities markets.

PARTIES

20. Lead Plaintiff Jason Solomon acquired Outlook securities at artificially inflated prices during the Class Period and was damaged upon the revelation of the alleged corrective disclosures. (ECF No. 24-3)

21. Additional Plaintiff Ramzy Alsaidi acquired Outlook securities at artificially inflated prices during the Class Period and was damaged upon the revelation of the alleged corrective disclosures. (ECF No. 1 at pp 31-33)

22. Additional Plaintiff Michael Lucas acquired Outlook securities at artificially inflated prices during the Class Period and was damaged upon the revelation of the alleged corrective disclosures. (ECF No. 23-3)

23. Additional Plaintiff Mariam Silverman, Trustee for the Mariam Silverman Trust UA Mar. 15, 1969, acquired Outlook securities at artificially inflated prices during the Class Period and was damaged upon the revelation of the alleged corrective disclosures. (ECF No. 23-3)

24. Defendant Outlook is a Delaware corporation with principal executive offices located at 485 Route 1 South, Building F, Suite 320, Iselin, New Jersey 08830. Outlook's common stock trades in an efficient market on the Nasdaq Stock Market ("NASDAQ") under the ticker symbol "OTLK".

25. Defendant C. Russell Trenary III ("Trenary") served as Outlook's Chief Executive Officer ("CEO") from July 2021 to the present.

26. Defendant Lawrence A. Kenyon ("Kenyon") has served as Outlook's Chief Financial Officer ("CFO") at all relevant times. Defendant Kenyon served as the Company's CEO, CFO and President from August 2018 to July 2021 when he

led Outlook's shift in business strategy from oncobiology to focus solely on ophthalmology.

27. Defendants Trenary and Kenyon are referred to herein collectively as the "Individual Defendants".

28. The Individual Defendants possessed the power and authority to control the contents of Outlook's SEC filings, press releases, and other market communications. The Individual Defendants were provided with copies of Outlook's SEC filings, press releases, and other market communications alleged herein to be misleading prior to or shortly after their issuance and had the ability and opportunity to prevent their issuance or to cause them to be corrected. Because of their positions with Outlook, and their access to material information available to them but not to the public, the Individual Defendants knew that the adverse facts specified herein had not been disclosed to and were being concealed from the public, and that the positive representations being made were then materially false and misleading. The Individual Defendants are liable for the false statements and omissions pleaded herein.

29. Outlook and the Individual Defendants are collectively referred to herein as "Defendants".

SUBSTANTIVE ALLEGATIONS

Age-Related Macular Degeneration

30. Age-related macular degeneration ("AMD") is an eye disease that can blur your central vision. AMD occurs when aging causes damage to the macula — the part of the eye that controls sharp, straight-ahead vision. The macula is part of the retina — the light-sensitive tissue at the back of the eye.

31. AMD is a common condition, and it is a leading cause of vision loss for older adults. AMD does not cause complete blindness, but losing the central vision can make it more difficult to see faces, read, drive, or do close-up work like cooking or fixing things around the house.

32. Most people with AMD have dry AMD (also called atrophic AMD). This is when the macula gets thinner with age. Dry AMD happens in 3 stages: early, intermediate, and late. It usually progresses slowly over several years. There is no treatment for late dry AMD.

33. Wet AMD (also called advanced neovascular AMD) is a less common type of late AMD that usually causes faster vision loss. Any stage of dry AMD can turn into wet AMD, but wet AMD is always late stage. It occurs when a protein called vascular endothelial growth factor ("VEGF") makes abnormal blood vessels grow in the wrong place in the back of the eye.

34. Two treatment options can slow down or stop vision loss from wet AMD: Anti-VEGF injections and photodynamic therapy.

35. Anti-VEGF injections are the most common treatment doctors prescribe and administer to slow vision loss from wet AMD. These medicines help stop bleeding and leaking from blood vessels in the back of the eye. Most patients with wet AMD are prescribed anti-VEGF injections as their only treatment. An individual anti-VEGF injection is usually effective in treating wet AMD for only a short period of time, so most patients treated with anti-VEGF injections require reoccurring injections to treat their symptoms.

36. Anti-VEGF injection therapies are also FDA and European Medicines Agency-approved for the treatment of many forms of cancer. These medications are frequently prescribed and administered for targeted cancer therapy and are typically combined with other medications.

37. In 2004, the FDA approved Genentech, Inc.'s ("Genentech") Avastin (bevacizumab), for the treatment of metastatic colorectal cancer. The approval was based on two pivotal Phase III clinical trials, including a total of 1385 patients. However, the FDA has never approved any formulation of bevacizumab for ophthalmic use.

38. In June 2006, the FDA approved Genentech's Lucentis (ranibizumab), for the treatment of wet AMD. The approval was based on two pivotal, Phase III clinical trials, including a total of 1139 patients.

39. In October 2006, the National Eye Institute of the National Institutes of Health announced that it would fund a comparative study trial of ranibizumab and bevacizumab to assess the relative efficacy and ocular adversity in treating wet AMD. In 2008, this study, called the Comparison of Age-Related Macular Degeneration Treatment Trials ("CATT Study"), enrolled approximately 1,200 patients with newly diagnosed wet AMD. The patients were assigned randomly to different treatment groups, and the data was collected from 2008 to 2009. The overall conclusions demonstrated no statistical difference between the treatment groups' outcomes after eight years. The CATT Study also provided guidance to the ophthalmology industry regarding the appropriate size of the clinical trial.

40. Thereafter, due to the positive results of the CATT Study, bevacizumab became a popular off-label option for the treatment of wet AMD. Bevacizumab's use in ophthalmology is "off-label" because it has not been through the rigorous FDA process required for approval to market bevacizumab with an indication to treat ophthalmic pathology.

41. Furthermore, Genentech does not produce bevacizumab in doses suitable for intravitreal injections necessary for treating wet AMD. Doctors must

rely on compounding pharmacies to create single-use vials of the appropriate doses for such treatments.

42. Compounded drugs are not FDA-approved and are generally exempt from pre-market drug approval cGMP. FDA does not verify the safety or effectiveness of compounded drugs. Compounded drugs, while higher risk, fill an important role for patients whose medical needs cannot be met by an FDA-approved drug product.

43. However, if bevacizumab were to be approved by the FDA for treatment of wet AMD and other ophthalmologic indications, then Sections 503A and 503B of the Federal Food, Drug and Cosmetic Act (the "FDCA") would generally prohibit compounding manufacturers from manufacturing single-use vials and syringes of bevacizumab. In that case, Outlook, as the drug sponsor, would then be the only entity authorized to market bevacizumab for those indications in the United States. Accordingly, approval had enormous benefits because (a) Outlook would be the only company authorized to sell the drug for the treatment of wet AMD, (b) approval would restrain competition from compounding pharmacies, and (c) Outlook would finally have a drug candidate that would generate revenue.

The FDA Approval Process

44. In the United States, pharmaceutical development and marketing is regulated by the FDA, an agency of the U.S. Department of Health and Human

Services. The modern regulatory regime was enacted in 1962, after Thalidomide, a sleeping pill, caused congenital disabilities in thousands of babies. In reaction to this tragedy, Congress passed the Kefauver-Harris Amendments to the FDCA, requiring that any company that wanted to market a pharmaceutical product in the United States (in industry parlance, a "sponsor") had to obtain prior approval from the FDA, and that the approval had to be based upon substantial scientific evidence demonstrating that the product was safe and effective for its intended use in humans.

45. The FDA divides therapeutics into different categories. Bevacizumab falls into a category known as "biologics," or large molecule drugs, because it is a monoclonal antibody. Biologics can only be marketed in the United States when the FDA has approved a BLA. This process is like the process to obtain approval for pharmaceuticals, or small molecule drugs, which are approved via a process known as a New Drug Application ("NDA").

46. Biologics like bevacizumab are considered "drugs" under the FDCA thus they are subject to requirements of the FDCA. *See* https://www.fda.gov/drugs/therapeutic-biologics-applications-bla/frequently-asked-questions-about-therapeutic-biological-products. As amended, that statute requires the Secretary of the FDA to refuse any drug application if:

> (a) "he has insufficient information to determine whether such drug is safe for use under such conditions;"

(b) "there is a lack of substantial evidence that the drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the proposed labeling thereof;" or

(c) "the methods used in, and the facilities and controls used for, the manufacture, processing, and packing of such drug are inadequate to preserve its identity, strength, quality, and purity."

21 U.S.C. § 355(d)(3)-(5).

47. The FDA is only permitted to consider clinical evidence to be "substantial," and thus satisfy the FDCA, if it:

> "consist[s] of adequate and well-controlled investigations, including clinical investigations, by experts qualified by scientific training and experience to evaluate the effectiveness of the drug involved, on the basis of which it could fairly and responsibly be concluded by such experts that the drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the labeling or proposed labeling thereof."

21 U.S.C. § 355(d). Well-controlled clinical investigations measure the subject drug against a control group, which is provided either a placebo or another recognized drug for comparison. Moreover, well-controlled clinical investigations are almost always conducted in a "double-blinded" manner in which neither study participants nor investigators (as well as the sponsor and associated research organizations) know whether each participant has been provided the candidate drug or is a member of the control group until the study concludes and the results are "unblinded." Double-

blinding is intended to minimize test bias and error that can arise when the participant and/or investigator have knowledge of the assigned treatment.

48. The FDA has long advised the industry that "[w]ith regard to quantity [of pivotal clinical trials], it has been FDA's position that Congress generally intended to require at least two adequate and well-controlled studies, each convincing on its own, to establish effectiveness." *See* "*Guidance for Industry: Providing Clinical Evidence of Effectiveness for Human Drug and Biological Products*," available at https://www.fda.gov/media/71655/download.

49. Biologics are also subject to the provisions of the Public Health Services Act (the "PHSA"). 42 U.S.C. § 262. Because of the complexity of manufacturing and characterizing a biologic, the PHSA emphasizes the importance of appropriate manufacturing control for products. The PHSA provides for a system of controls over all aspects of the manufacturing process. In some cases, manufacturing changes could result in changes to the biological molecule that might not be detected by standard chemical and molecular biology characterization techniques yet could profoundly alter the safety or efficacy profile. Therefore, changes in the manufacturing process, equipment or facilities may require additional clinical studies to demonstrate the product's continued safety, identity, purity and potency.

50. The PHSA requires that a BLA be approved only "on the basis of a demonstration that – (I) "the biological product that is the subject of the application is safe, pure, and potent; and (II) the facility in which the biological product is manufactured, processed, packed, or held meets standards designed to assure that the biological product continues to be safe, pure, and potent." 42 U.S.C. § 262(a)(2)(C).

51. The PHSA clarifies that its requirements are in addition to those enumerated by FDCA and other regulations. 42 U.S.C. § 262(j).

52. Prior to conducting any clinical research in humans, a sponsor must screen the proposed biologic for toxicity with animal studies, and file an Investigational New Drug ("IND") application with the FDA. An IND application includes the following information:

> (a) Animal pharmacology and toxicology studies sufficient to permit an assessment as to whether the product is reasonably safe for initial testing in humans. Any previous experience with the drug in humans (such as use in foreign countries) also must be included.
>
> (b) Manufacturing information describing the composition, manufacturer, stability, and controls used for manufacturing the drug substance and the drug product. This information is assessed to ensure that the company can adequately produce and supply consistent batches of the drug.
>
> (c) Clinical protocols and investigator information including sufficient detail regarding the proposed protocols for clinical studies to assess whether the initial-phase trials will expose human subjects to unnecessary risks.

21 C.F.R. § 312.23. After filing an IND, the sponsor must wait 30 days before commencing human clinical trials.

53. The sponsor, not the FDA, is responsible for determining the design of clinical trials and the protocols for each trial. If a sponsor wants the FDA to agree to the sufficiency of a particular protocol, the sponsor may request a Special Protocol Assessment ("SPA") pursuant to 21 U.S.C. § 355(b)(5)(C). Under this provision, the FDA and sponsor meet to discuss the sponsor's proposed protocols and reduce any agreements to writings that become part of the administrative record. Such agreements may not be changed except by mutual consent or under exceptional medical or scientific circumstances. *Id*. Outlook did not apply for and did not receive any SPA's in connection with the NORSE 1, NORSE 2, or NORSE 3 clinical trials.

54. A sponsor generally conducts clinical trials in three phases. These phases, which are codified in FDA regulations, are as follows:

> (a) Phase I. Phase I studies "are designed to determine the metabolism and pharmacologic actions of the drug in humans, the side effects associated with increasing doses, and, if possible, to gain early evidence on effectiveness. The total number of subjects and patients included in Phase 1 studies varies with the drug, but is generally in the range of 20 to 80."
>
> (b) Phase II. Phase II studies are "typically well controlled" studies "conducted to evaluate the effectiveness of the drug for a particular indication or indications in patients with the disease or condition under study and to determine the common short-term side effects and risks

> associated with the drug." Phase II studies are "conducted in a relatively small number of patients, usually involving no more than several hundred subjects."
>
> (c) Phase III. Phase III studies are expanded studies "performed after preliminary evidence suggesting effectiveness of the drug has been obtained, and are intended to gather the additional information about effectiveness and safety that is needed to evaluate the overall benefit-risk relationship of the drug and to provide an adequate basis for physician labeling. Phase 3 studies usually include from several hundred to several thousand subjects."

21 C.F.R. § 312.21. A Phase III clinical trial is also sometimes called a "pivotal" clinical trial, referring to its importance to a marketing application. Such trials are "conducted in a larger and often more diverse target population in order to demonstrate and/or confirm efficacy and to identify and estimate the incidence of common adverse reactions." *See* Umsched, *et al*., "*Key Concepts of Clinical Trials: A Narrative Review*," available at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3272827/.

55. When a sponsor believes it has conducted sufficient well-controlled clinical trials and believes that those trials demonstrate substantial evidence of efficacy and safety consistent with the FDCA, the sponsor may prepare and file a BLA with the FDA seeking approval to market the subject drug in a specific dose for the treatment of a specific condition or indication. The BLA must also specify how the drug will be manufactured, packaged and labeled. The FDA can only grant

approval when presented with scientific evidence meeting the requisite statutory criteria.

56. Within sixty (60) days of receiving a BLA, the FDA will accept the BLA for filing if it believes the BLA is sufficiently complete to permit a substantive review of the information contained within the BLA. The acceptance of a BLA for filing is not a determination of the substantive merits of the BLA, but rather a threshold determination of whether there is enough data to conduct a substantive examination. If the BLA determines a facial problem preventing a meaningful substantive examination – for example, if the BLA is missing paperwork, fails to include data in the proper format, or suffers from other facial errors that make review impossible – the FDA may refuse to file the BLA.

57. The filing of a BLA triggers review deadlines specified in the Prescription Drug User Fee Act ("PDUFA"), enacted in 1992 and reauthorized by amendment every five years thereafter. Under the PDUFA, the FDA is generally required to respond to the BLA within six months. The date by which the FDA must issue its response is frequently referred to as a drug candidate's "PDUFA date."

58. A BLA accepted for filing is reviewed for substance by the FDA's Center for Drug Evaluation & Research ("CDER") when a biologic drug candidate consists of monoclonal antibodies, such as bevacizumab.

59. Once the BLA is submitted to the FDA for review, a critical part of the FDA's review includes inspecting the drug manufacturer's facilities to ensure that the drug manufacturer can produce commercial quantities of the drug candidate in accordance with manufacturing regulations.

60. Because biologics manufacturing is often substantially more difficult and inconsistent than traditional pharmaceuticals, FDA regulations impose strict requirements that proper manufacturing practices be proved before approval. Specifically, 21 C.F.R. § 601.2(d) provides that BLA approvals require "a determination that the establishment(s) and the product meet applicable requirements to ensure the continued safety, purity, and potency of such products. Applicable requirements for the maintenance of establishments for the manufacture of a product subject to this section shall include but not be limited to the good manufacturing practice requirements." *Id.*

61. The requirement to show good manufacturing practices is well known and repeated throughout FDA regulations governing biologics. For example, FDA regulations clarify that: "A biologics license application shall be approved only upon examination of the product and upon a determination that the product complies with the standards established in the biologics license application and the requirements prescribed in the regulations in this chapter including but not limited to the good manufacturing practice requirements set forth in parts 210, 211, 600, 606, and 820

of this chapter." 21 C.F.R. § 601.20(a). FDA regulations also require that the biologic be "available for inspection during all phases of manufacture," 21 C.F.R. § 601.20(b)(2) and that "[n]o product shall be licensed if any part of the process of or relating to the manufacture of such product…would impair the assurances of continued safety, purity, and potency as provided by the regulations contained in this chapter," 21 C.F.R. § 601.20(c).

62. The FDA ensures the quality of drug products by carefully monitoring drug manufacturers' compliance with cGMP regulations. The cGMP regulations for drugs contain minimum requirements for the methods, facilities, and controls used to manufacture, process, and pack a drug product. The regulations ensure that a product is safe for use and has the ingredients and potency it claims to have.

63. The approval process for new and generic drug marketing applications includes a review of the manufacturer's compliance with the cGMP. FDA assessors and investigators determine whether the firm has the necessary facilities, equipment, and ability to manufacture the drug it intends to market.

64. When the FDA inspects a drug manufacturing facility and finds violations in cGMP, the FDA notifies the facility of each observed violation via Form 483. Form 483s can be obtained through a FOIA request served on the FDA or through private third-party databases.

65. If the FDA approves the biologic drug candidate, it will issue an approval letter in writing to the sponsor. If the FDA finds that the BLA fails to provide the substantial evidence of efficacy and safety required by statute, or has other material shortcomings preventing approval, the FDA will send the sponsor a CRL identifying the reasons why the application was not approved. A CRL may, but need not always, suggest that the sponsor conduct additional clinical trials.

66. CRLs are never made public by the FDA when issued and are never released thereafter as long as the sponsor is continuing to pursue the subject drug application.[3] Accordingly, investors must rely on the sponsor companies to provide accurate information regarding CRLs.

67. A sponsor may continue to pursue approval of a drug candidate after receiving a CRL by resubmitting its BLA within a year, or longer if extended. A BLA resubmission is also called the sponsor's "complete response" to the CRL because it is supposed to respond to all the deficiencies identified in the CRL and the sponsor is supposed to indicate on the cover page of the resubmission that it does so. Within 14 days after filing, a resubmission is classified either as a class 1 resubmission or a class 2 resubmission, depending upon its content, and assigned a new PDUFA date.

[3] The FDA sometimes releases CRLs in redacted form years later, after the drug candidate is approved or officially abandoned.

FDA's Wet AMD Approval History and Guidance

68. The FDA will, from time to time, release guidance prepared for FDA staff, the regulated industry, and/or the public that describes the FDA's interpretation of, or policy on, a regulatory issue. Unlike statutes and regulations, guidance cannot generally create legally binding requirements.

69. There are two types of guidance: Level 1 guidance and Level 2 guidance. Level 1 guidance: (a) set forth initial interpretations of statutory or regulatory requirements, (b) set forth changes in interpretation or policy that are of more than a minor nature, (c) include complex scientific issues, or (d) cover highly controversial issues. In contrast, Level 2 guidance clarifies or restates existing practices or minor changes in interpretation or policy.

70. FDA's Good Guidance Practices regulation (21 C.F.R. §10.115) governs the development and issuance of guidance documents, and it gives interested persons a number of opportunities to provide input into the guidance development process.

71. Generally, the FDA solicits public input on Level 1 guidance prior to implementation. The Agency posts draft Level 1 guidance documents on its website and publicizes them by issuing a Notice of Availability ("NOA") of the draft guidance in the *Federal Register*.

72. Generally, the public has 60 days to provide comments to the FDA on draft guidance. In some instances, FDA may also hold public meetings or workshops on draft Level 1 guidance to solicit additional comments or present the draft Level 1 guidance to an advisory committee for review. Once the comment period has closed, the Agency reviews and considers the comments it has received, as it prepares the final guidance. The Agency also posts final Level 1 guidance documents on its website and publicizes them by publishing an NOA in the *Federal Register*.

73. On February 6, 2023, the FDA published a guidance regarding the eligibility criteria, trial design considerations and efficacy endpoints of clinical trials for drug candidates aimed at treating wet AMD, titled *Neovascular Age-Related Macular Degeneration: Developing Drugs for Treatments Guidance for Industry* (the "Wet AMD Guidance").[4] On the same day, the FDA published an NOA in the *Federal Register*.

74. With regards to efficacy considerations, the Wet AMD Guidance recommends that "***safety and efficacy should be demonstrated in at least two adequate and well-controlled, multicenter trials*** utilizing different investigative

[4] Available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/neovascular-age-related-macular-degeneration-developing-drugs-treatment.

sites," and that a "decrease in the number of administrations of available effective therapies alone is not sufficient for the demonstration of efficacy."

75. In order to satisfy the safety requirement, the Wet AMD Guidance recommends:

> (a) ***That approximately 400 or more patients using the investigational drug complete treatment*** with a concentration of the investigational drug at least as high as proposed for marketing and with a dosing frequency at least as frequent as proposed for marketing.
>
> (b) Before submission of a marketing application, ***the sponsor should ensure that at least 300 patients have completed at least 9 months of follow-up after the initiation of treatment***.
>
> (c) FDA recommends that at least one concurrently controlled safety trial be conducted for at least 2 years' duration.

76. Even before the Wet AMD Guidance was issued, it was well-known throughout the ophthalmic drug industry that pivotal trials to support successful applications for wet AMD therapies required significant patient populations and multiple Phase III trials. Indeed, ***every*** wet AMD approval has involved multiple Phase III trials, with generally more than 700 patients:

Wet AMD Treatment	Year of FDA Approval	Number of Patients Enrolled
Macugen	2004	1190 patients across two pivotal Phase III trials
Lucentis	2006	1139 patients across two pivotal Phase III trials
Eylea	2011	2457 patients across two pivotal Phase III pivotal trials
Beovu	2019	1817 patients across two pivotal Phase III trials

Vabysmo	2022	1329 patients across two pivotal Phase III trials
Izervay	2023	734 patients across two pivotal Phase III trials

77. Each of the above, previously FDA-approved wet AMD treatments conducted at least two large, well-controlled clinical studies as prescribed in the Wet AMD Guidance.

Outlook and Bevacizumab

78. Outlook is a late clinical-stage biopharmaceutical company focusing on developing and commercializing monoclonal antibodies for various ophthalmic indications. The Company's lead product candidate is ONS-5010, an ophthalmic formulation of the antibody bevacizumab for treating wet AMD and other retina diseases.

79. Prior to focusing on the ophthalmology market, Outlook was known as Oncobiologics, Inc., and described itself as a clinical-stage biopharmaceutical company focused on identifying, developing, manufacturing, and commercializing complex biosimilar therapeutics to monoclonal antibodies, or mAbs, in the disease areas of immunology and oncology.

80. On August 2, 2018, Outlook signaled that it would shift away from oncology and focus solely on ophthalmology. On the same day, the Company announced in a press release that Defendant Kenyon was appointed CEO and

President and that he would be an "ideal fit" as the Company moved ONS-5010 "into the clinic."

81. On November 6, 2018, the Company announced that it had commenced its first clinical study for ONS-5010 outside of the United States, later termed "NORSE 1." NORSE 1 enrolled only 61 patients in nine sites around Australia. As the Company later admitted in a press release issued August 26, 2020, NORSE 1 was only a "small study" aimed at providing "proof-of-concept." At no time did the Company reach agreement with the FDA through a SPA or otherwise that such a small, underpowered study would provide proof of efficacy sufficient to support approval.

82. On December 3, 2018, the Company issued a press release announcing that it formally changed its name to Outlook Therapeutics, Inc. Defendant Kenyon explained that "the timing of this corporate rebranding effectively signals the significance of the recent strategic shift in the business and the high value opportunity we are pursuing in the anti-VEGF ophthalmic market."

83. On March 1, 2019, the Company announced that it submitted an IND application to the FDA for ONS-5010. Once again, the Company assured investors that:

> ***"[NORSE 2] is the second of two adequate and well controlled Phase 3 clinical trials evaluating ONS-5010*** against ranibizumab (Lucentis®) for wet AMD. [NORSE 2] was recently initiated in Australia and is expected to begin enrolling patients in Australia and New Zealand in

> March 2019 and in the United States (once the IND is effective) in April 2019 ***for a total of at least 180 patients***. "Enrollment in [NORSE 1], ***the first of the two Phase 3 wet AMD clinical trials for ONS-5010***, is being conducted in Australia and is expected to complete enrollment in March 2019 with ***a total of at least 60 patients***."

84. According to Outlook, it expected to enroll a combined total of 240 patients for the NORSE 1 and NORSE 2 Phase III pivotal trials.

85. On April 1, 2019, the Company followed up with a press release announcing that the FDA had accepted the IND application for ONS-5010. Once again, the Company described the NORSE 2 trial:

> ***[NORSE 2] is the second of two adequate and well controlled Phase 3 clinical trials evaluating ONS-5010*** against ranibizumab (Lucentis®) for wet AMD and ***will enroll approximately 180 patients*** (90 in each arm). Patients enrolled in the [NORSE 2] study will be treated for 11 months. The primary outcome of the study is a statistically significant improvement in mean visual acuity of five letters or more for ONS-5010 over ranibizumab.

86. On June 3, 2019, the Company announced that it had signed a master services agreement with FUJIFILM Diosynth Biotechnologies ("FujiFilm") for the production of ONS-5010. Defendant Trenary stated:

> "Our master services agreement with [FujiFilm] secures ***a world class manufacturing facility for the potential commercial launch of ONS-5010***. Most importantly, [FujiFilm] ***has the ability to rapidly scale manufacturing of ONS-5010 while maintaining the quality controls that meet or exceed regulatory requirements***. ***Identifying a highly-regarded manufacturing partner for ONS-5010 is an important part of our commercialization strategy and is a required part of the Biologics License Application, or BLA, submission in wet AMD***."

87. In the same press release, the Company touted FujiFilm's manufacturing capacity:

> ***[FujiFilm] is focused on combining technical leadership in cell culture, microbial fermentation and viral vectors with world class GMP manufacturing facilities to advance tomorrow's medicines***. For over 25 years they have been supporting customers with the development and manufacture of recombinant proteins, viral vaccines and gene therapies.

And FujiFilm CEO, Gerry Fareell of the College Station, Texas manufacturing facility, added:

> "We are pleased that Outlook Therapeutics has selected FUJIFILM Diosynth Biotechnologies to partner in the commercial development of ONS-5010.

88. On August 14, 2019, the Company issued a press release announcing its financial and operational results for the third quarter ended June 30, 2019. In that press release, the Company formally announced renaming its two Phase III clinical trials to NORSE 1 and NORSE 2 from ONS-5010-001 and ONS-5010-002, respectively. The Company also announced that NORSE 2 was expected to enroll 220 patients, up from 180 patients, reflecting Defendants' knowledge that smaller trials would not be sufficient.

89. In the same press release, Defendant Kenyon endorsed FujiFilm's manufacturing capacity:

> "I am confident that our engagement of FUJIFILM Diosynth Biotechnologies as the global producer of ONS-5010 puts us in a

> stronger position for commercialization as we look past the clinical development program and towards seeking regulatory approvals."

90. On August 20, 2019, the Company issued a press release and assured investors that "[t]he ***NORSE 1 study design was confirmed in our April 2018 FDA meeting to be one of our two adequate and well controlled clinical trials*** required to support approval of ONS-5010 to treat wet AMD."

91. On June 17, 2020, the Company represented that the FDA had accepted the study design of the NORSE 1 and NORSE 2 trials at an April 2018 End-of-Phase 2 meeting. However, the FDA never entered into any SPA or other agreement providing that successful results from trials that small would provide sufficient evidence of efficacy to support a BLA, without an additional clinical trial of a scale implemented by every other sponsor that had received approval for a wet AMD treatment.

92. On September 30, 2020, the Company announced its partnership with Ajinomoto bio-Pharma Services ("Ajinomoto") "to provide product manufacturing in the best-in-class cGMP global manufacturing facilities." The Company further added that it had "completed technology transfer and scale-up consistent with global cGMP standards with both Fuji and [Ajinomoto]."

93. In order for Outlook to obtain approval for the ONS-5010 BLA it would have to (1) submit substantial evidence from two well-controlled Phase III pivotal

trials with an adequate amount of patients and (2) prove that its manufacturers, FujiFilm and Ajinomoto, comply with cGMP regulations.

94. On June 10, 2021, Ajinomoto received a Form 483 from the FDA, which was available to Defendants and other members of the public, after inspections of its San Diego, California facility from May 5, 2021 to May 25, 2021. Attached hereto as **Exhibit 1**. The Form 483 identified three observations of cGMP violations:

(a) The separate or defined areas and control systems necessary to prevent contamination or mix-ups were deficient.

(b) Equipment and utensils were not cleaned and sanitized at appropriate intervals to prevent contamination that would alter the safety, identity, strength, quality, or purity of the drug product.

(c) Written specifications for laboratory controls did not include a description of the testing procedures used.

95. On August 31, 2021, FujiFilm received a Form 483 from the FDA, which was available to Defendants and other members of the public, after inspections of its College Station, Texas facility from August 23, 2021 to August 31, 2021. Attached hereto as **Exhibit 2**. The Form 483 identified nine observations of cGMP violations:

(a) There were not adequate controls to prevent cross-contamination of other products in its multiproduct facility.

(b) Failed to adequately investigate batch contamination.

(c) No quantitative or specific measurements had been taken to determine the equipment used in bulk drug substance manufacturing.

(d) The facility was not following its contamination control strategy for its products.

(e) Inadequate data integrity corrective measures.

(f) No procedures/policies required identity testing of cell banks that have been received from outside sources.

(g) Inadequate handling of inventory and misuse of facilities.

(h) Failed to perform routine corrective maintenance to assess whether PM plans need to be changes or determining the need for re-qualification of equipment, utilities, or facilities.

(i) Missing training records and inadequate training for employees that manufacture bulk substance.

96. On January 16, 2023, Ajinomoto received another Form 483 from the FDA, which was available to Defendants and other members of the public, after inspection of its San Diego, California facility from January 11-13, and January 16, 2023. Attached hereto as **Exhibit 3**. The Form 483 identified two observations of cGMP violations:

(a) The building filling line capping and [redacted] machine was validated using only one batch run and not three. The quality control microbiology laboratory's cGMP material ambient storage room was not qualified for 20-25 degrees Celsius.

(b) Facility and equipment maintenance were deficient in their ability to support cGMP production activities.

97. On June 7, 2023, FujiFilm received another Form 483 from the FDA, which was available to Defendants and other members of the public, after inspections of its College Station, Texas facility from May 31, 2023 to June 7, 2023. Attached hereto as **Exhibit 4**. The Form 483 identified eight observations of cGMP violations:

> (a) The responsibilities and procedures applicable to the quality control unit were not fully followed, specifically that the quality systems in place were inadequate to prevent the use of critical quality analytical test methods and protocols that had not been appropriately validated or released for use in testing to ensure product quality, potency, identity, and quality.
>
> (b) Control procedures which validate the performance of those manufacturing processes that may be responsible for causing variability of drug substances were inadequate.
>
> (c) Laboratory controls did not include the establishment of scientifically sound and appropriate standards designed to assure that drug substances conformed to appropriate standards of identity, strength, quality, and purity.
>
> (d) Failed to thoroughly review and document unexplained discrepancies.
>
> (e) Manufacturing process areas were deficient regarding the system for monitoring environmental conditions.
>
> (f) The control systems necessary to prevent contamination or mix-ups were deficient.
>
> (g) Failed to establish adequate written procedures.
>
> (h) Failed to exercise appropriate controls over computer or related systems to ensure data generated cannot be deleted.

Materially False and Misleading Statements Issued During the Class Period

98. The Class Period begins on August 3, 2021, when the Company issued a press release highlighting the outcome of its NORSE 2 trial. In that press release, Trenary stated:

> "The successful ***completion of this trial is the final step needed in our clinical evaluation of ONS-5010 to enable us to submit a Biologics License Application to the FDA*** in the first calendar quarter of next year."

The press release further stated:

> "In meeting both the primary and key secondary endpoints in NORSE TWO with highly significant clinically relevant results, ***we have achieved the requirements agreed upon with the FDA, and when combined with our previously reported clinical trial results, this completes the clinical package necessary for the submission of our BLA.***"

99. The statements identified in Paragraph 98 above were materially false and/or misleading when made because: (a) the NORSE 2 trial was not "the final step" required for the Company's BLA submission; (b) the clinical package was not then "complete"; (c) Outlook had not "achieved the requirements agreed upon with the FDA"; (d) the FDA had never agreed that clinical trials as small as NORSE 1 and NORSE 2 would be sufficient to demonstrate efficacy to support approval for the ONS-5010 BLA and no other wet AMD treatment had been approved on such meager evidence of efficacy; and (e) the statements omitted that the FDA required

evidence that the manufacturers of ONS-5010 complied with cGMP to approve the ONS-5010 BLA, which Outlook did not have.

100. On the same day, the Company conducted a call with investors and analysts regarding the Company's topline results for its NORSE 2 trial, which Defendants Kenyon and Trenary attended. Defendant Trenary touted the results and stated that "[t]his is the final step we needed in order to prepare, to have what we need to prepare, and move forward with our US FDA BLA preparation."

101. The statements identified in 100 above were materially false and/or misleading when made because: (a) the NORSE 2 trial was not "the final step" required for the Company's BLA submission; (b) the statements omitted that the FDA had never agreed that clinical trials as small as NORSE 1 and NORSE 2 would be sufficient to demonstrate efficacy, and no other wet AMD treatment had been approved on such meager evidence of efficacy; and (c) the statements omitted that the FDA required evidence that the manufacturers of ONS-5010 complied with cGMP to approve the ONS-5010 BLA, which Outlook did not have.

102. At the same conference call, Defendant Trenary touted the Company's manufacturing partnerships with FujiFilm and Ajinomoto:

> We're not growing alone. ***We have partners on the manufacturing side and on the product development side that the company has been dealing with and working with and will continue to do so. FUJIFILM Diosynth and Aji biopharma are both excellent partners that company has been working without a manufacturing standpoint and will continue to do so***, and in addition to that, the company has a

> product line research and development debt associated with new delivery systems, this is a device that ends up being put in the hands of retinal surgeons, and yet for the segment that we're stepping into, the syringes and needles were not specifically designed and tested and FDA-approved for use and treatment of wet macular degeneration in the retinal space. We will step in with a product, ultimately, that does include a prefilled syringe with materials, needles, et cetera, that are all specified and designed specifically for these treatments. ***So again, it's not just the FDA approval, but we're also bringing high-quality partners*** and a product development effort that we believe will enhance the quality of care -- has the potential to enhance the quality of care in this space.

103. The statements identified in Paragraph 102 above were materially false and/or misleading when made because: (a) Ajinomoto was not an "excellent" or "high-quality partner"; and (b) the statements omitted that on June 10, 2021 Ajinomoto had received a Form 483 setting forth numerous violations of cGMP.

104. On August 13, 2021, the Company filed with the SEC a form 10-Q Quarterly Report, signed by Defendant Kenyon and stated the following about the NORSE trials:

> Our clinical program for ONS-5010 in wet AMD involves three clinical trials, which we refer to as NORSE ONE, NORSE TWO and NORSE THREE. We reported achieving the anticipated safety and efficacy and positive proof-of-concept topline results from NORSE ONE, a clinical experience study, in August 2020. NORSE TWO is our pivotal Phase 3 clinical trial comparing ONS-5010 to ranibizumab (LUCENTIS). The topline results reported from NORSE TWO in August 2021 showed that ONS-5010 met the primary and key secondary endpoint for efficacy with clinically impactful change observed for treated patients. The NORSE TWO primary endpoint difference in proportion of subjects gaining at least 15 letters BCVA was met and was highly statistically significant and clinically relevant. In the intent-to-treat (ITT) primary dataset, the percentage of patients who gained at least 15

> letters who were treated with ranibizumab was 23%, and the percentage of patients who gained at least 15 letters who were treated with ONS-5010 was 41% (p = 0.0052). The primary endpoint was also statistically significant and clinically relevant in the secondary per-protocol (PP) dataset (p = 0.04) where the percentages were almost identical, at 24% with ranibizumab and 41% with ONS-5010. The key secondary endpoint BCVA score change from baseline to month 11 in the primary ITT dataset was also highly statistically significant and clinically relevant (p = 0.0043). A mean change in BCVA was observed with ranibizumab of 5.8 letters and the mean change with bevacizumab-vikg was 11.2 letters. The results were also statistically significant in the secondary PP dataset (p = 0.05) with a mean change in letters with ranibizumab of 7.0 letters and with bevacizumab-vikg 11.1 letters. NORSE THREE is an open-label safety study we conducted to ensure the adequate number of safety exposures to ONS-5010 are available for the initial ONS-5010 Biologics License Application, or BLA, filing with the FDA. In March 2021 we reported that the results from NORSE THREE provided a positive safety profile for ONS-5010. ***Accordingly, all three of these clinical trials required for our planned BLA submission in the first quarter of calendar 2022 for wet AMD have been completed.***

105. The statements identified in Paragraph 104 above were materially false and/or misleading when made because they omitted the following material information: (a) that the FDA indicated that the BLA should include a second pivotal efficacy trial in addition to the NORSE 2 trial, sized in accordance with other approved treatments, which Outlook did not include; (b) as a result, the company lacked substantial evidence of efficacy to support its BLA submission for ONS-5010; (c) the Company lacked necessary evidence that the selected manufacturers of ONS-5010 complied with cGMP; and (d) as a result of these deficiencies, Outlook

lacked the necessary evidence to obtain approval for its BLA at the time the statements were made.

106. On September 13, 2021, Defendant Trenary attended the HC Wainwright 23rd Annual Global Investment Conference and was questioned about the data from the NORSE 2 trial, to which Trenary responded:

> "Yeah, ***so this was, the company is engaged in three very important clinical trials in order to gain FDA approval. This was a plan that was put together between the company and the FDA and***, as you know, Doug, the first study and the third study or the so-called NORSE 1 and NORSE 3 had already been completed, showed good safety and efficacy. ***One was a really nice trial that gave them a window into both safety and efficacy and the other one was an open-label safety study***. So NORSE 2 really became the pivotal study, and this was the one that we just announced results on 228 patients were enrolled. The trial was conducted completely in the United States. Over 95% of the patients were treatment naive, so they'd never been treated for any retinal disorder before, and as you'll see from the data, the results were really impactful."

107. The statements identified in Paragraph 106 above were materially false and/or misleading when made because: (a) BLA submission based on the three trials discussed, NORSE 1, 2 and 3 was not "a plan put together with the company and the FDA"; (b) the statements omitted that NORSE 1-3 trials were not sufficiently scaled to demonstrate substantial evidence of ONS-5010's efficacy and safety; (c) the statements omitted that the FDA had never agreed that clinical trials as small as NORSE 1-3 would be sufficient to demonstrate efficacy, and no other wet AMD treatment had been approved on such meager evidence of efficacy; (d) the statements

omitted that the FDA indicated that the BLA should include a second pivotal efficacy trial in addition to the NORSE 2 trial, sized in accordance with other approved treatments, which Outlook did not include; (e) the statements omitted that the Company lacked necessary evidence that the selected manufacturers of ONS-5010 complied with cGMP; and (f) as a result of (a) through (e), the Company lacked sufficient evidence "to gain FDA approval" for ONS-5010.

108. During the presentation, Trenary explained the importance of maintaining manufacturing partners with facilities that satisfy the FDA's cGMP for ophthalmology substances and stated that in order "to get FDA approval in ophthalmology for a drug that's going to be injected in someone's eye, there are standards that have to be met. These standards relate to sterility, to PH, to osmolarity, potency, and all of these requirements are things that we just have to meet all of those in order to get an FDA approval in ophthalmology for these conditions."

109. At the same presentation, analyst Doug Zhou asked a question regarding the Company's key milestones in the next six months, to which Defendant Trenary assured the Company's manufacturing partners met the FDA's cGMP regulations:

> "***We also believe we've got a remarkably good opportunity to have a really first-class launch in the United States***. This is a space that does not need hundreds of sales reps, so we think we can put together an affordable sales organization that has dozens rather than hundreds of

> reps that are out there. The 3PLs that are out there now, those third parties are amazing in their quality and the relationships that they have throughout the marketplace. ***We've got first-class manufacturers. We are working with both Ajinomoto as well as Fuji and so the product quality that's coming out of our factories, partially that was used in our clinical trials, is outstanding.***"

110. The statements identified in Paragraph 109 above were materially false and/or misleading when made because: (a) FujiFilm and Ajinomoto were not an "first-class manufacturers" and their "product quality" was not "outstanding"; (b) the statements omitted that on June 10, 2021, the FDA documented in a Form 483 that Ajinomoto had numerous violations of cGMP; (c) the statements omitted that on August 31, 2021, the FDA documented in a Form 483 that FujiFilm had numerous violations of cGMP; and (d) the statements omitted that the Company lacked evidence that FujiFilm and Ajinimoto complied with cGMP.

111. On September 28, 2021, Cantor Fitzgerald hosted Defendant Trenary at a fireside chat. Trenary touted his experience and expertise in the ophthalmology field, and specifically:

> "Yeah, so I've been involved in what at the time were four of the ten largest launches in the history of medical devices in ophthalmology. And they ranged from intraocular lens implants to lasers to phacoemulsification equipment. So it's really, my experience has kind of run the gamut. And for my first big launch, I was the director of marketing and for my last big launch, I was a company president of a $500 million division. So there are a lot of moving parts when you're gearing up for a launch that's going to be $50 million or $100 million or more, and it involves making sure that you've got all the right pieces in place for your sales and marketing effort, the right pieces in place on the clinical and regulatory side because that's ultimately what kick-

> starts and what ultimately allows you to be able to get the FDA approval and get across the finish line. And then of course the work that takes place within the company or within your factories, all very important aspects to ensure that you've got the right kind of volume and the ability to meet demand for launches that are this large."

112. Cantor biotechnology analyst Kristen Kluska asked pointed questions about the comparison between the NORSE trials and the CATT Study:

> **Q – Kristen Kluska:** What were the main goals of the earlier reported in NORSE 1 and NORSE 3 trials including in comparison to the CATT study and safety to support your BLA package?
>
> **A – Russ Trenary:** Yeah, so great question. The NORSE 1 and NORSE 3 studies were very instructive to the company before we engaged in our pivotal trial, which was NORSE 2. ***The NORSE 1 trial, Kristin, was a trial that included dozens of patients in Australia***. ***It was a clinical experience trial***, and what the company was looking for at the time was, would the Outlook Therapeutics formulation of bevacizumab provide the signals in safety and efficacy that would warrant going forward through the rest of the clinical trial phase? And the company got the signals it was looking for in both safety and efficacy.
>
> ***Now knowing that it takes a large number of patients from a safety standpoint to garner FDA approval, the company conducted a NORSE 3 trial, which was an open label safety study***. And what the company learned was in both NORSE 1 and NORSE 3, there were no cases of ocular inflammation. And so, the safety signals were spectacular, and ***the numbers, the end was high that there were enough patients in that open label safety study to set the company up to make A BLA submission if NORSE 2 two turned out to be successful***.

113. The statements identified in Paragraph 112 above were materially false and/or misleading when made because: (a) the NORSE 1 and 3 trials were not comparable to the CATT Study; (b) there were not "enough patients" enrolled in the NORSE 1-3 trials to make a successful BLA submission; (c) and the CATT Study

had 1,208 patients enrolled while NORSE 1 trial had only 61 patients, NORSE 2 had only 228 patients and the NORSE 3 trial only had 195 patients; and (d) the statements omitted that FDA guidelines called for two pivotal efficacy trials for AMD treatments sized in accordance with other approved treatments.

114. Defendant Trenary further touted ONS-5010's ability to obtain FDA approval:

> "Bevacizumab is not approved by the FDA for any use in ophthalmology. ***We'll be the first. We have an original BLA filing, we'll be the first FDA approved in ophthalmology bevacizumab***. And so because of the standards we have to meet in ophthalmology, we think it's going to be a game changer in that segment."

115. The statements identified in Paragraph 114 above were materially false and/or misleading when made because: (a) the Company was not then positioned to "be the first" approval for bevacizumab in ophthalmology; and (b) the statements omitted that the FDA had never agreed that clinical trials as small as NORSE 1-3 would be sufficient to demonstrate efficacy, and no other wet AMD treatment had been approved on such meager evidence of efficacy; and (c) the statements omitted that the FDA indicated that the BLA should include a second pivotal efficacy trial in addition to the NORSE 2 trial, sized in accordance with other approved treatments, which Outlook had not conducted.

116. In response to specific questions regarding the manufacturing aspect of the BLA application, Defendant Trenary assured that the Company was aware of the

FDA's cGMP requirements and that its manufacturing partners would satisfy those requirements:

> **Q – Kristen Kluska**: Okay, great. So now that you have the data you need across these three trials that we discussed, could you please remind us of the timelines for your BLA submission in addition to some of the pre-commercial work that your team is conducting?
>
> **A – Russ Trenary**: Yeah, so we're going through ***putting together all of the requirements for the BLA associated with CMC, all of our chemistry and manufacturing and control test methods and test results in order to make those part of the BLA filing***, which we expect to be in the first quarter of next year.

117. Defendant Trenary went on to tout his experience and expertise, as well as that of the Company's manufacturing partners, FujiFilm and Ajinomoto.

> ***So fortunately, we've partnered with some first-class drug manufacturers who have all the capacity you could ever need. We've already scaled up our drug substance so that it's already being produced in commercial quantities***. And so I think having lived through these experiences of having to hire in a new sales team, get the marketing, the non-manpower piece ready, get the factories ready, having done that a number of times, there's almost no substitute for that. ***After you've lived through these, it's a lot easier to anticipate the unanticipated because something good or bad has happened to you in the past, and you need to learn the lessons from that. So I think those four huge launches I've had are going to come in handy in this case as well.***

118. The statements identified in Paragraphs 116 and 117 above were materially false and/or misleading when made because: (a) FujiFilm and Ajinomoto were not "first class drug manufacturers"; (b) the Company could not meet the "requirements for the BLA associated with CMC [chemistry, manufacturing and

control]"; (c) the statements omitted that on June 10, 2021, the FDA documented in a Form 483 that Ajinomoto had numerous violations of cGMP; and (d) the statements omitted that on August 31, 2021, the FDA documented in a Form 483 that FujiFilm had numerous violations of cGMP.

119. In the last question of the fireside chat, analyst Kluska inquired about any other takeaways that the listeners should be aware of, to which, Defendant Trenary admitted understanding the importance of cGMP in the approval of ophthalmology treatments: "[t]he requirements around osmolarity and drug concentration and pH and all the cGMP standards that we have to live to in ophthalmology, even the ophthalmologist, they know there's a difference."

120. On September 28, 2021, the Company issued a press release reporting the safety data from the NORSE 2 trial. With regards to the manufacturing of ONS-5010, the Company touted its manufacturing partners:

> In anticipation of potential FDA marketing approval in 2022 for ONS-5010, Outlook Therapeutics has begun commercial launch planning, ***including manufacturing with drug substance manufacturer FUJIFILM Diosynth Biotechnologies and best-in-class drug product manufacturer Aji Biopharma Services***, distribution, sales force planning, physician and payor advisory board outreach, key opinion leader support and payor community engagement.

121. The statements identified in Paragraph 120 above were materially false and/or misleading when made because: (a) Ajinomoto was not a "best-in-class drug product manufacturer"; (b) the statements omitted that on June 10, 2021, the FDA

documented in a Form 483 that Ajinomoto had numerous violations of cGMP; and (c) the statements omitted that on August 31, 2021, the FDA documented in a Form 483 that FujiFilm had numerous violations of cGMP.

122. On December 22, 2021, the Company issued a press release reporting its financial results for fiscal year 2021. In that press release, the Company touted its manufacturing partnerships:

> In anticipation of potential FDA marketing approval in 2022 for ONS-5010, Outlook Therapeutics has begun commercial launch planning, including ***manufacturing with drug substance manufacturer FUJIFILM Diosynth Biotechnologies and best-in-class drug product manufacturer Aji Biopharma Services***, distribution, sales force planning, physician and payor advisory board outreach, key opinion leader support and payor community engagement.

123. The statements identified in Paragraph 122 above were materially false and/or misleading when made because: (a) Ajinomoto was not a "best-in-class drug product manufacturer"; (b) the statements omitted that on June 10, 2021, the FDA documented in a Form 483 that Ajinomoto had numerous violations of cGMP; and (c) the statements omitted that on August 31, 2021, the FDA documented in a Form 483 that FujiFilm had numerous violations of cGMP.

124. On December 23, 2021, the Company filed with the SEC a form 10-K Annual Report, signed by Defendants Trenary and Kenyon. In that filing, the Company made numerous statements acknowledging the FDA's cGMP requirements regarding the manufacturing of ONS-5010:

> Manufacturers and manufacturing facilities are required to comply with extensive FDA, and comparable foreign regulatory authority, requirements, including ensuring that quality control and manufacturing procedures conform to current Good Manufacturing Practices, or cGMP, regulations. As such, our current and future manufacturing partners will be subject to continual review and inspections to assess compliance with cGMP and adherence to commitments made in any non-disclosure agreement, BLA or marketing authorization application.

125. The statements identified in Paragraph 124 above were materially false and/or misleading when made because: (a) the statements omitted that the Company lacked evidence that its selected manufacturers complied with cGMP; (b) the statements omitted that on June 10, 2021, the FDA documented in a Form 483 that Ajinomoto had numerous violations of cGMP; and (c) the statements omitted that on August 31, 2021, the FDA documented in a Form 483 that FujiFilm had numerous violations of cGMP.

126. In that same filing the Company acknowledged the risk that if FujiFilm or Ajinomoto failed to comply with the FDA's cGMP regulations, then the ONS-5010 BLA could be jeopardized: "Our business could be harmed if our new contract manufacturer is unable to manufacture our product candidates at the necessary quantity or quality levels."

127. The Company then assured that FujiFilm's and Ajinomoto's manufacturing facilities complied with the FDA's cGMP regulations:

Manufacturing

We are working with FujiFilm Diosynth Biotechnologies, or Fuji, and Ajinomoto Bio-pharma Services, or AjiBio, to provide product manufacturing in current Good Manufacturing Practices, or cGMP, manufacturing facilities. We have also executed a supply agreement for a best-in-class pre-filled ophthalmic syringe, which we believe will provide both ease-of-use for clinicians and add to ONS-5010's safety profile over the current unapproved therapies that have caused problems related to syringe malfunction, contamination, etc. We will screen other contract manufacturers to meet our clinical, commercial and regulatory supply requirements as needed. For a discussion of risks related to our sources and availability of supplies, please see "Risk Factors—Previously, we manufactured bulk drug substance for preclinical and clinical supplies of our product candidates in our in-house facility. ***Our business could be harmed if our new contract manufacturer is unable to manufacture our product candidates at the necessary quantity or quality levels,.***" and "Risk Factors—We currently engage single source suppliers for clinical trial services and multiple source suppliers for future drug substance manufacturing, fill-finish manufacturing and product testing of ONS-5010. The loss of any of these suppliers, or any future single source suppliers, could harm our business."

128. The statements identified in Paragraphs 126 and 127 above were materially false and/or misleading when made because: (a) the statements omitted that the Company lacked evidence that its selected manufacturers complied with cGMP; (b) the statements omitted that on June 10, 2021, the FDA documented in a Form 483 that Ajinomoto had numerous violations of cGMP; (c) the statements omitted that on August 31, 2021, the FDA documented in a Form 483 that FujiFilm had numerous violations of cGMP; and (d) the risk that FujiFilm or Ajinomoto

would violate the FDA's cGMP regulations was not hypothetical but had already materialized.

129. On January 10, 2022, Defendant Trenary attended a presentation organized by HC Wainwright and, in response to a pointed question about the NORSE trials, assured that the Company had consulted and complied with the FDA's requirements regarding the NORSE trials:

> **Q – Doug Tsao**: So why don't we talk about the approval process for Lytenava or your Bevacizumab. You've obviously now reported strong results from your pivotal study. So how does that position you and where are you in terms of preparation for filing your BLA?
>
> **A – Russ Trenary**: Yeah, so the filing of the BLA is really soon. We're going to be doing that this quarter. ***And what the company did was, in consultation with FDA and in communication with FDA, designed a three-study program in order to get approval for our version of bevacizumab***. There was a clinical experience trial that was performed initially that really informed the company of how our product would perform. ***And as expected, the results of it were very similar to what you would see in the literature over the last 14, 15 years pertaining to bevacizumab results***.

130. The statements identified in Paragraph 129 above were materially false and/or misleading when made because: (a) the referenced NORSE 1-3 trials were not designed to meet FDA requirements "in order to get approval" for ONS-5010; (b) the statements omitted that the FDA had never agreed to approve based on the small clinical trials of NORSE 1- 3, and had not communicated that those trials were sufficient for approval, and no other wet AMD treatment had been approved on such meager evidence of efficacy; (c) the statements omitted that the Company lacked

substantial evidence of efficacy necessary to support approval for ONS-5010; and (d) the statements omitted that the Company lacked sufficient evidence that the manufacturers of its drug would comply with cGMP necessary to support approval for ONS-5010.

131. At the same event, analyst Doug Tsao asked Defendant Trenary regarding the comparison between the NORSE trials and the CATT Study:

> **Q – Doug Tsao**: And when you look at this data and the strength of it, what do you think, sort of... And clearly I think the results were even better than you sort of might've assumed. And really the study I think was sort of designed around the effect that you had typically seen from your previous studies with CATT and so forth. And what do you think might've helped get somewhat incrementally better results versus prior studies that were relying on compounded Avastin?
>
> **A – Russ Trenary:** Yeah. So I think there's probably a couple of things. ***I mean, in all fairness, part of this would be associated with trial design, right?*** So when we performed the study, the bevacizumab arm, we did monthly injections of bevacizumab, ***which is comparable to what all the other companies did in order to gain FDA approval for their drug.*** So we needed to do that. Having said that, getting almost 43% of the patients with three-line gainers was, by any measure, fantastic.

132. The statements identified in Paragraph 131 above were materially false and/or misleading when made because: (a) the NORSE 1-3 trials were not "comparable to what all the other companies did in order to gain FDA approval for their drug"; (b) no other wet AMD treatment had been approved on such meager evidence of efficacy on such a small population of patients; (c) the statements omitted that the Company lacked substantial evidence of efficacy necessary to

support approval for ONS-5010; and (d) the statements omitted that the Company lacked sufficient evidence that the manufacture of its drug would comply with cGMP necessary to support approval for ONS-5010.

133. On January 25, 2022, Defendant Trenary attended the Virtual Investor Conference, where he touted the results of the NORSE trials:

> ***We're going to bring the first FDA approval for bevacizumab in ophthalmology***. It's meaningful because there's a difference in what you have to do to earn the right to actually inject a drug solution into a patient's eye. There are standards that I'll go through in a later slide that are just now required for off-label bevacizumab, which was originally designed to go into a drip IV and treat oncology.
>
> ***We're going to meet those standards***. We did in our clinical trial. I think when you see the clinical data, maybe we can connect the dots, see why are those data so good?
>
> ***
>
> Then, finally, just the level of product differentiation that we're going to be able to bring here. ***I think we're going to be able to deliver a pristine level of safety and efficacy and a bevacizumab that nobody's ever seen before. One that's at top of its game, one that meets all the FDA standards***.
>
> ***
>
> What we wanted to show was that we'll get a great result with monthly injections like everybody else, and then we were going to try to show superiority within the clinical trial of the ranibizumab arm. Doesn't mean we'd get a marketing claim, because obviously you could argue we got a superior treatment regimen, ***but if we could show superiority between those two arms ... This strategy had been revealed to FDA by Terry. There was agreement that, yeah, that is a legitimate control arm to use.***

134. The statements identified in Paragraph 133 above were materially false and/or misleading when made because: (a) the Company would not "bring the first FDA approval for Bevacizumab in ophthalmology;" (b) the NORSE trials did not "meet[] all FDA standards"; (c) the statements omitted that the Company lacked substantial evidence of efficacy necessary to support approval for ONS-5010; (d) the statements omitted that the Company lacked sufficient evidence that the manufacture of its drug would comply with cGMP necessary to support approval for ONS-5010; and (e) the FDA had never agreed that clinical trials as small as NORSE 1-3 would be sufficient to demonstrate efficacy to support approval for the ONS-5010 BLA.

135. Furthermore, at the January 25, 2022 Virtual Investor Conference, Defendant Trenary touted FujiFilm's and Ajinomoto's ability to meet the FDA's cGMP requirements:

> FDA will be reviewing our stability that supports our shelf life. They'll be looking at the particulate amount in our drug solution. They'll be looking at our pH levels, the drug potency, our osmolarity specifications, our endotox levels, and all the other things that go into being a cGMP approved ... Having those cGMP approved facilities, processes, and products.
>
> Everything in green, we have to check those boxes. ***We did check those boxes in order to use the drug solution that was injected during the clinical trials. We think we bring a level, of pristine level, of safety and efficacy partially associated to meeting the requirements that FDA makes you meet in ophthalmology***.

136. The statements identified in Paragraph 135 above were materially false and/or misleading when made because: (a) the Company had not met FDA cGMP requirements "in order to use the drug solution that was injected during the clinical trials"; (b) the statements omitted that the Company lacked evidence that its selected manufacturers complied with cGMP; (b) the statements omitted that on June 10, 2021, the FDA documented in a Form 483 that Ajinomoto had numerous violations of cGMP; (c) the statements omitted that on August 31, 2021, the FDA documented in a Form 483 that FujiFilm had numerous violations of cGMP; and (d) the statements omitted that the Company lacked substantial evidence of efficacy necessary to support approval for ONS-5010.

137. On February 14, 2022, the Company issued a press release announcing its financial and operational results for the first quarter of fiscal year 2022. In that press release, the Company once again touted the manufacturing capacities of FujiFilm and Ajinomoto:

> In anticipation of potential FDA marketing approval in 2022 for ONS-5010, Outlook Therapeutics has begun commercial launch planning, ***including a partnership with FUJIFILM Diosynth Biotechnologies for our drug substance and best-in-class drug product manufacturer Aji Biopharma Services for our drug product***, plus distribution, sales force planning, physician and payor advisory board outreach, key opinion leader support and payor community engagement.

138. The statements identified in Paragraph 137 above were materially false and/or misleading when made because: (a) the statements omitted that the Company

lacked evidence that its selected manufacturers complied with cGMP; (b) the statements omitted that on June 10, 2021, the FDA documented in a Form 483 that Ajinomoto had numerous violations of cGMP; and (c) the statements omitted that on August 31, 2021, the FDA documented in a Form 483 that FujiFilm had numerous violations of cGMP.

139. In the same press release, the Company touted the manufacturing capacities of FujiFilm and Ajinomoto:

> In anticipation of potential FDA marketing approval in late 2022 or early 2023, ***Outlook Therapeutics has begun commercial launch planning, including best-in-class partnerships with FUJIFILM Diosynth Biotechnologies for drug substance, and with drug product manufacturer Aji Biopharma Services for finished drug product***.

140. The statements identified in Paragraph 139 above were materially false and/or misleading when made because: (a) neither FujiFilm nor Ajinimoto was "best-in-class"; (b) the statements omitted that the Company lacked evidence that its selected manufacturers complied with cGMP; (c) the statements omitted that on June 10, 2021, the FDA documented in a Form 483 that Ajinomoto had numerous violations of cGMP; and (d) the statements omitted that on August 31, 2021, the FDA documented in a Form 483 that FujiFilm had numerous violations of cGMP.

141. On May 13, 2022, the Company issued a press release and once again touted the manufacturing capacities of FujiFilm and Ajinomoto:

> In anticipation of potential FDA marketing approval in early 2023, ***Outlook Therapeutics has begun commercial launch planning,***

> ***including best-in-class partnerships with FUJIFILM Diosynth Biotechnologies for drug substance, and with drug product manufacturer Aji Biopharma Services for finished drug product.*** The Company also is actively building out its distribution and commercial team structures.

142. The statements identified in Paragraph 141 above were materially false and/or misleading when made because: (a) neither FujiFilm nor Ajinimoto was "best-in-class"; (b) the statements omitted that the Company lacked evidence that its selected manufacturers complied with cGMP; (c) the statements omitted that on June 10, 2021, the FDA documented in a Form 483 that Ajinomoto had numerous violations of cGMP; and (d) the statements omitted that on August 31, 2021, the FDA documented in a Form 483 that FujiFilm had numerous violations of cGMP.

143. On the same day, the Company's Chief Operations Officer attended the Retina World Congress, where he affirmatively stated: "I'm the chief operations officer for Outlook Therapeutics. ***We're a pre-commercial stage pharmaceutical company that will be getting the first FDA approved ophthalmic bevacizumab***."

144. The statements identified in Paragraph 143 above were materially false and/or misleading when made because they omitted: (a) that the Company lacked substantial evidence of efficacy necessary to support approval for ONS-5010; (b) the statements omitted that the Company lacked sufficient evidence that the manufacture of its drug would comply with cGMP necessary to support approval for

ONS-5010; and (c) as a result of (a) and (b), the Company had not submitted sufficient evidence to obtain approval for ONS-5010 in its BLA.

145. On May 31, 2022, the Company issued a press release announcing that the FDA requested additional information regarding the Company's ONS-5010 BLA submission:

> Outlook Therapeutics, Inc. (Nasdaq: OTLK), a pre-commercial biopharmaceutical company working to develop and launch the first FDA-approved ophthalmic formulation of bevacizumab for use in retinal indications, today announced that the U.S. Food and Drug Administration (FDA) has requested additional information in order to complete the filing of the Company's Biologics License Application (BLA) for ONS-5010/ LYTENAVA™ (bevacizumab-vikg) for the treatment of wet age-related macular degeneration (wet AMD). Outlook Therapeutics has voluntarily withdrawn its BLA for ONS-5010 and is actively working to respond to the FDA's request. The Company plans to re-submit a revised BLA by September 2022.

146. In that same release, the Company stated:

> Based on a compilation of the data from its previously completed clinical trials – NORSE ONE, NORSE TWO and NORSE THREE – Outlook Therapeutics submitted the BLA to the FDA in March 2022. NORSE ONE, a proof-of-concept and clinical experience trial, helped validate the protocols and approach for NORSE TWO, the pivotal safety and efficacy trial. The NORSE TWO data were statistically significant and clinically relevant for the primary and all secondary endpoints. ***NORSE THREE was an open-label supplementary safety trial conducted to ensure that a sufficient number of patients had been dosed with ONS-5010 ophthalmic bevacizumab to support the regulatory submission***.

147. The statements identified in Paragraph 146 above were materially false and/or misleading when made because they omitted: (a) that the Company lacked

substantial evidence of efficacy necessary to support approval for ONS-5010; (b) that NORSE 1-3 did not have "a sufficient number of patients had been dosed with ONS-5010 ophthalmic bevacizumab to support the regulatory submission;" (d) that the Company lacked sufficient evidence that the manufacture of its drug would comply with cGMP necessary to support approval for ONS-5010; and (e) as a result of (a) – (d), the Company had not submitted sufficient evidence to obtain approval for ONS-5010 in its BLA.

148. On June 14, 2022, the Company issued a press release announcing:

> As previously announced, Outlook Therapeutics submitted its BLA for ONS-5010 to the FDA in March 2022 and subsequently voluntarily withdrew its submission in May 2022 to provide additional information requested by the FDA. Following receipt of further correspondence from the FDA, Outlook Therapeutics has confirmed the additional information necessary to re-submit the BLA for ONS-5010.

149. The statements identified in Paragraph 148 above were materially false and/or misleading when made because the statements omitted that: (a) the "additional information necessary to re-submit the BLA for ONS-5010" required a second pivotal clinical trial, which the Company had not completed; (b) the FDA had never agreed that clinical trials as small as NORSE 1-3 would be sufficient to demonstrate efficacy to support approval for the ONS-5010 BLA; (c) that the Company lacked substantial evidence of efficacy necessary to support approval for ONS-5010; and (d) that the Company lacked sufficient evidence that the

manufacturers of its drug would comply with cGMP necessary to support approval for ONS-5010.

150. On August 10, 2022, the Company issued a press release reporting its financial and operational results for the third quarter for fiscal year 2022. In that press release, Defendant Trenary stated:

> "***We have received invaluable line-of-sight related to the additional requirements for a successful ONS-5010 BLA re-submission. Following productive feedback from the FDA, we established a clear path forward and are highly focused on executing the necessary items to meet our planned re-submission by September of this year***. Additionally, we continue to position ourselves operationally and financially for the potential FDA approval and subsequent launch of ONS-5010. Our confidence in its potential remains unwavering. If approved, ONS-5010 would be the first FDA-approved ophthalmic formulation of bevacizumab, avoiding the public health risk to patients of off-label treatment of bevacizumab. We believe there is value in achieving the strict safety and efficacy requirements associated with an FDA approval, and we expect to meet these standards."

151. The statements identified in Paragraph 150 above were materially false and/or misleading when made because the statements omitted that (a) the "line-of-sight related to the additional requirements for a successful ONS-5010 BLA re-submission" required a second pivotal clinical trial sized in accordance with other approved treatments, which the Company had not completed; (b) that the Company lacked substantial evidence of efficacy necessary to support approval for ONS-5010; (c) that the Company lacked sufficient evidence that the manufacturers of its drug would comply with cGMP necessary to support approval for ONS-5010; (d) the

Company had not then established a "clear path forward" without an additional clinical trial; and (e) the Company was not then "highly focused on executing the necessary items" to resubmit its BLA by "September of th[at] year" because it had neither resolved cGMP problems nor conducted the necessary additional trial.

152. On August 30, 2022, the Company issued a press release reporting that it had resubmitted its ONS-5010 BLA to the FDA. In that press release, Defendant Trenary stated:

> Over the past three months, ***we have worked diligently to provide the additional required information that was not included in our March 2022 BLA submission, to address requests from the Agency to ensure our BLA is complete for acceptance and review. We believe that this re-submission addresses each of the comments and recommendations from the Agency, and we are confident in the revised BLA application."***

The press release further touted the results of the NORSE trials:

> "***Our NORSE TWO pivotal trial for ONS-5010 showed compelling efficacy and clinical relevance coupled with a robust safety profile***, and we are confident that our investigational drug, if approved, will be a valuable therapeutic option to treat retina diseases."

153. The statements identified in Paragraph 152 above were materially false and/or misleading when made because: (a) the re-submission did not "address requests from the Agency to ensure our BLA is complete for acceptance and review;" (b) the re-submission did not address "each of the comments and recommendations from the Agency;" and (c) the NORSE trials were not sufficient to meet the required efficacy and safety endpoints.

154. In the same release, the Company compared the NORSE trial findings with those of the CATT Study and other studies for FDA-approved indications of bevacizumab:

> Safety results across the first three NORSE trials demonstrated a strong benefit-to-risk safety profile. Across all three ONS-5010 registration trials, there was only one ocular inflammation adverse event, which was reported in NORSE TWO; the event was treated topically and resolved without sequelae. The most common adverse reaction (≥ 5%) reported in patients receiving ONS-5010 was conjunctival hemorrhage associated with the needle injection procedure (5%). ***These safety findings continue to support minimal ocular inflammation and safety signals consistent with what was previously reported in the 2011 CATT trial (National Eye Institute) and other large adequate and well-controlled ophthalmic studies of bevacizumab.***

155. The statements identified in Paragraph 154 above were materially false and/or misleading when made because: (a) the statements omitted that the NORSE trials referenced were not comparable with the CATT Study or other trials for FDA-approved indications of bevacizumab.

156. In the same press release, the Company, touted the manufacturing capacities of FujiFilm and Ajinomoto:

> In anticipation of potential FDA marketing approval in 2023, ***Outlook Therapeutics has continued its commercial launch planning. These activities include establishing best-in-class partnerships with FUJIFILM Diosynth Biotechnologies for drug substance***, and with drug product manufacturer Ajinomoto Bio-pharma Services for finished drug product. Outlook Therapeutics is also actively building out its distribution and commercial capabilities.

157. The statements identified in Paragraph 156 above were materially false and/or misleading when made because the statements omitted that: (a) the Company lacked evidence that its selected manufacturers complied with cGMP; (b) on June 10, 2021, the FDA documented in a Form 483 that Ajinomoto had numerous violations of cGMP; and (c) on August 31, 2021, the FDA documented in a Form 483 that FujiFilm had numerous violations of cGMP.

158. On October 28, 2022, the Company issued another press release and touted its BLA re-submission:

> "We are pleased the FDA has begun its review of our application. ***ONS-5010 is designed and manufactured to be fully compliant with the FDA's criteria for ophthalmic intravitreal biologics*** and we are excited about the prospect of filling the public health need for an FDA-approved ophthalmic formulation of bevacizumab."

159. The statements identified in Paragraph 158 above were materially false and/or misleading when made because the statements omitted that (a) the Company's application for a BLA was incomplete and required a second pivotal clinical trial, which the Company had not completed; (b) that the Company lacked substantial evidence of efficacy necessary to support approval for ONS-5010; (c) that the Company lacked sufficient evidence that the manufacturers of its drug would comply with cGMP necessary to support approval for ONS-5010; and (d) that ONS-5010 was not "designed and manufactured to be fully compliant with FDA's criteria for ophthalmic intravitreal biologics.

160. In the same press release, the Company again touted the "best-in-class partnerships" with FujiFilm and Ajinomoto:

> Outlook Therapeutics also established best-in-class partnerships with FUJIFILM Diosynth Biotechnologies for drug substance manufacturing, and with drug product manufacturer Ajinomoto Bio-Pharma Services for finished drug product.

161. The statements identified in Paragraph 160 above were materially false and/or misleading when made because: (a) neither FujiFilm nor Ajinimoto was "best-in-class"; (b) the statements omitted that the Company lacked evidence that its selected manufacturers complied with cGMP; (c) the statements omitted that on June 10, 2021, the FDA documented in a Form 483 that Ajinomoto had numerous violations of cGMP; and (d) the statements omitted that on August 31, 2021, the FDA documented in a Form 483 that FujiFilm had numerous violations of cGMP.

162. On December 29, 2022, the Company filed with the SEC a Form 10-K Annual Report, signed by Defendants Trenary and Kenyon. In that filing, the Company made numerous statements acknowledging the competitiveness of the AMD space and specifically mentioned FDA-approved treatments:

> The current FDA approved market leaders for the treatment of wet AMD are VEGF inhibitors, including EYLEA, BEOVU, LUCENTIS, SUSVIMO and VABYSMO. Recently, BYOOVIZ was approved and launched which will be followed by CIMERLI, both ranibizumab biosimilars.

***

> The initial recently approved biosimilar versions of LUCENTIS are also expensive, although they are available at a discount to the reference drug. Bevacizumab, BYOOVIZ, CIMERLI, EYLEA, BEOVU, LUCENTIS and VABYSMO are all administered via intravitreal injections directly into the eye. SUSVIMO is an implantable refillable port delivery system that delivers anti-VEGF for 4-6 months, upon which the device is refilled.

163. The statements identified in Paragraph 162 above were materially false when made because they omitted that the referenced FDA-approved AMD treatments cited in the 2022 10-K were based on pivotal efficacy trials with a population size much greater than that of the NORSE trials and in accordance with FDA guidance, *see* ¶ 76 for a comparative chart of FDA-approved wet AMD treatments.

164. In the 2022 10-K, the Company further stated that the NORSE 1 trial, with 61 patients, "was designed as a randomized, masked clinical experience trial and ***served as the first of our two required registration clinical trials to support our BLA submission*** with the FDA for ONS-5010 for the treatment of wet AMD."

165. The statements identified in Paragraph 164 above were materially false and/or misleading when made because: (a) the statements omitted that the NORSE 1 trial data was not sufficiently sized to serve as a pivotal clinical trial; and (b) as a result, the Company then lacked sufficient evidence of efficacy from "two required registration clinical trials to support [its] BLA submission."

166. The Company further assured that its manufacturing partners, FujiFilm and Ajinomoto, could provide cGMP-compliant manufacturing:

> **Manufacturing**
>
> ***We are working with FujiFilm Diosynth Biotechnologies, or Fuji, and Ajinomoto Bio-pharma Services, or AjiBio, to provide product manufacturing in current Good Manufacturing Practices, or cGMP, manufacturing facilities***. We have also executed a supply agreement for a best-in-class pre-filled ophthalmic syringe, which we believe will provide both ease-of-use for clinicians and add to ONS-5010's safety profile over the current unapproved therapies that have caused problems related to syringe malfunction and contamination. We will screen other contract manufacturers to meet our clinical, commercial and regulatory supply requirements as needed.

167. The statements identified in Paragraph 166 above were materially false and/or misleading when made because the statements omitted that: (a) the Company lacked evidence that its selected manufacturers complied with cGMP; (b) on June 10, 2021, the FDA documented in a Form 483 that Ajinomoto had numerous violations of cGMP; and (c) on August 31, 2021, the FDA documented in a Form 483 that FujiFilm had numerous violations of cGMP.

168. In the same filing, the Company included language purportedly disclosing risks regarding its manufacturing partners:

> For a discussion of risks related to our sources and availability of supplies, please see "Risk Factors—Previously, we manufactured bulk drug substance for preclinical and clinical supplies of our product candidates in our in-house facility. Our business could be harmed if our current contract manufacturer is unable to manufacture our product candidates at the necessary quantity or quality levels." and "Risk Factors—We currently engage single source suppliers for clinical trial

> services and multiple source suppliers for future drug substance manufacturing, fill-finish manufacturing and product testing of ONS-5010. The loss of any of these suppliers, or any future single source suppliers, could harm our business."
>
> ***
>
> We rely on third parties to manufacture and test ONS-5010, conduct our preclinical and clinical trials and perform other tasks for us. If these third parties do not successfully carry out their contractual duties, meet expected deadlines or comply with regulatory requirements, we may not be able to obtain regulatory approval for or commercialize our product candidates and our business could be harmed.

169. The statements identified in Paragraph 168 above were materially false and/or misleading when made because: (a) the risk that FujiFilm or Ajinomoto would violate the FDA's cGMP regulations was not hypothetical but had already materialized; (b) the statements omitted that the Company lacked evidence that its selected manufacturers complied with cGMP; (c) the statements omitted that on June 10, 2021, the FDA documented in a Form 483 that Ajinomoto had numerous violations of cGMP; (d) the statements omitted that on August 31, 2021, the FDA documented in a Form 483 that FujiFilm had numerous violations of cGMP; and (e) the risk that FujiFilm or Ajinomoto would violate the FDA's cGMP regulations was not hypothetical but had already materialized.

170. On February 14, 2023, Outlook issued a press release and touted the manufacturing capacities of FujiFilm and Ajinomoto:

> In anticipation of potential FDA marketing approval in 2023, ***Outlook Therapeutics has begun commercial launch planning, including***

> ***best-in-class partnerships with FUJIFILM Diosynth Biotechnologies for drug substance***, and with drug product manufacturer Aji Bio-pharma Services for the finished drug product.

171. The statements identified in Paragraph 170 above were materially false and/or misleading when made because: (a) neither FujiFilm nor Ajinimoto was "best-in-class"; (b) the statements omitted that the Company lacked evidence that its selected manufacturers complied with cGMP; (c) the statements omitted that on June 10, 2021, the FDA documented in a Form 483 that Ajinomoto had numerous violations of cGMP; (d) the statements omitted that on January 16, 2023, the FDA documented in a Form 483 that Ajinomoto had numerous violations of cGMP; and (e) the statements omitted that on August 31, 2021, the FDA documented in a Form 483 that FujiFilm had numerous violations of cGMP.

172. On May 15, 2023, the Company issued a press release and touted the manufacturing capacities of FujiFilm and Ajinomoto using identical language as set forth in Paragraph 170, which were materially false and misleading when made for the reasons set forth in Paragraph 171.

173. On July 28, 2023, Defendant Trenary attended an event on age-related macular degeneration hosted by Chardan Capital Markets LLC. Defendant Trenary affirmatively stated, "[a]s far as we know we've provided all necessary information in both clinical as well as CMC in order to earn approval."

174. The statements identified in Paragraph 173 above were materially false and/or misleading when made because: (a) the Company had not "provided all necessary information in both clinical as well as CMC in order to earn approval"; (b) the statements omitted that the Company lacked evidence that its selected manufacturers complied with cGMP; (c) the statements omitted that on June 10, 2021, the FDA documented in a Form 483 that Ajinomoto had numerous violations of cGMP; (d) the statements omitted that on January 16, 2023, the FDA documented in a Form 483 that Ajinomoto had numerous violations of cGMP; (e) the statements omitted that on August 31, 2021, the FDA documented in a Form 483 that FujiFilm had numerous violations of cGMP; (f) the statements omitted that on June 7, 2023, the FDA documented in a Form 483 that FujiFilm had numerous violations of cGMP; and (g) statements omitted that the FDA had never agreed that clinical trials as small as NORSE 1-3 would be sufficient to demonstrate efficacy, and no other wet AMD treatment had been approved on such meager evidence of efficacy.

175. In response to a pointed question about the Company's manufacturing partners, Defendant Trenary assured that the Company had worked directly with FujiFilm and Ajinomoto to ensure their respective compliance with FDA cGMP regulations, including analyzing their CMC capabilities and executing mock FDA inspections:

> **Q – Host**: So in terms of manufacturing, so youre utilizing manufacturing partners to make Letenova can you comment whether

all the necessary FDA inspections have been completed, any other outstanding CMC issues?

A – Trenary: Yes, so we have not been given the marketplace blow by blow on when FDA's gone in for factory inspections or clinical site inspections or things like that. ***But I will say that we think we've got two great factory partners in FujiFilm Diosynth in their location in College Station, Texas and in Ajinomoto Biopahrma with their location in San Diego. Both are experienced companies in this whole area. We have found their CMC capabilities to be outstanding. We did a lot of work with them on mock inspections. We went through both of their factories several times with our mock inspection teams that we hired and just felt all along like both of those companies had great capability to not only run a clean shop but be in a position to do what needs to be done to get through FDA inspections in really good shape. So we're confident in those folks and believe that they've got all the capabilities required to get us to the finish line.***

176. The statements identified in Paragraph 175 above were materially false and/or misleading when made because: (a) the Company had not secured "two great factory partners"; (b) the statements omitted that the Company lacked evidence that its selected manufacturers complied with cGMP; (c) the statements omitted that on June 10, 2021, the FDA documented in a Form 483 that Ajinomoto had numerous violations of cGMP; (d) the statements omitted that on January 16, 2023, the FDA documented in a Form 483 that Ajinomoto had numerous violations of cGMP; (e) the statements omitted that on August 31, 2021, the FDA documented in a Form 483 that FujiFilm had numerous violations of cGMP; and (f) the statements omitted that on June 7, 2023, the FDA documented in a Form 483 that FujiFilm had numerous violations of cGMP.

177. On August 10, 2023, Defendant Trenary attended an event hosted by Ophthalmology Innovation Source where he touted, for the 17th time, the manufacturing capabilities of FujiFilm and Ajinomoto:

> Our factory partners that we're working with are Fujifilm Diosynth and Ajinomoto. ***These are both seasoned companies who have been through the paces with FDA. We have tremendous confidence in their ability to get through successful FDA audits***.

178. The statements identified in Paragraph 177 above were materially false and/or misleading when made because: (a) the statements omitted that the Company lacked evidence that its selected manufacturers complied with cGMP; (b) the statements omitted that on June 10, 2021, the FDA documented in a Form 483 that Ajinomoto had numerous violations of cGMP; (c) the statements omitted that on January 16, 2023, the FDA documented in a Form 483 that Ajinomoto had numerous violations of cGMP; (d) the statements omitted that on August 31, 2021, the FDA documented in a Form 483 that FujiFilm had numerous violations of cGMP; and (e) the statements omitted that on June 7, 2023, the FDA documented in a Form 483 that FujiFilm had numerous violations of cGMP.

The Truth Emerges

179. On May 31, 2022, the Company issued a press release announcing that the FDA requested additional information regarding the Company's ONS-5010 BLA submission.

180. As a result of this partial disclosure and/or the materialization of concealed risks, the Company's stock price declined by nearly 6.96% from its previous day closing price of $1.15 on May 31, 2022, to close at $1.07 on June 1, 2022, on heavy trading volume.

181. On August 30, 2023, during pre-market hours, Outlook issued a press release announcing that the FDA had issued a CRL to the ONS-5010 BLA and could not approve the ONS-5010 BLA during the present review cycle because of unresolved CMC and manufacturing site inspection issues, as well as "a lack of substantial evidence". Specifically, that press release stated, in relevant part:

> [T]he U.S. [FDA] has issued a CRL to the Company's BLA for ONS-5010, an investigational ophthalmic formulation of bevacizumab under development to treat wet AMD. While the FDA acknowledged the NORSE TWO pivotal trial met its safety and efficacy endpoints, ***the Agency concluded it could not approve the BLA during this review cycle due to several CMC issues, open observations from pre-approval manufacturing inspections, and a lack of substantial evidence***.
>
> "We continue to believe in the public health need to provide the retina community with an FDA-approved bevacizumab treatment option for wet AMD. We will request a formal meeting as soon as possible with the FDA to further understand the BLA deficiencies and how best to resolve them. Following this meeting with the FDA, the Company will be able to discuss next steps and the expected timing for resolution," said Russell Trenary, President and CEO of Outlook Therapeutics.

182. On this news, Outlook's stock price fell $1.141 per share, or 80.92%, to close at $0.269 per share on August 30, 2023.

183. As a result of Defendants' wrongful acts and omissions, and the resulting precipitous decline in the market value of the Company's securities, Plaintiffs and other Class members have suffered significant damages.

ADDITIONAL ALLEGATIONS OF SCIENTER

184. Several facts demonstrate that Defendants knowingly made false statements or, at a minimum, acted with reckless disregard for the truth or falsity of their Class Period representations to investors.

185. Defendants repeatedly stressed throughout their SEC filings that ONS-5010 was Outlook's sole clinical stage product, and without it, the Company could not be profitable. As such, ONS-5010 was a core operation of Outlook. That factor, in combination with other facts, contributes to an inference of scienter.

186. Defendants' own statements to investors show that they had access to information about the deficient size of the NORSE 1-3 trials and the cGMP issues with FujiFilm and Ajinomoto. For example, as alleged in Paragraph 175, Defendant Trenary stated that the Company had worked directly with FujiFilm and Ajinomoto to ensure their respective compliance with FDA cGMP regulations, including analyzing their CMC capabilities and executing mock FDA inspections to gauge each facility's readiness for an FDA inspection. During the purported inspections, the Defendants would no doubt have inquired about any Form 483 FujiFilm and Ajinomoto had received. *See also* ¶ 110 ("to get FDA approval in ophthalmology

for a drug that's going to be injected in someone's eye, there are standards that have to be met … and all of these requirements are things that we just have to meet all of those in order to get an FDA approval); ¶ 116 ("putting together all of the requirements for the BLA associated with CMC, all of our chemistry and manufacturing and control test methods and test results in order to make those part of the BLA filing"); ¶ 119 ("[t]he requirements around osmolarity and drug concentration and pH and all the cGMP standards that we have to live to in ophthalmology"); ¶ 175 (stating that Defendants conducted multiple mock FDA inspections of the FujiFilm and Ajinomoto manufacturing facilities).

187. Thus, Defendants had access to information about FujiFilm's and Ajinomoto's manufacturing facilities and their respective abilities to comply with cGMP. If Defendants did not inquire about FujiFilm's and Ajinomoto's cGMP compliance, then Defendants acted with reckless disregard when they disseminated representations regarding each manufacturer's ability to comply with cGMP.

188. In another example, as alleged in Paragraph 146, on May 31, 2022, the Company issued a press release announcing that the FDA had requested additional information regarding the ONS-5010 BLA. In that release, Defendant Trenary stated that the NORSE 3 "trial [was] conducted to ensure that a sufficient number of patients had been dosed with ONS-5010 ophthalmic bevacizumab to support the regulatory submission." *See also* ¶ 112 ("… the numbers, the end was high that

there were enough patients in that open label safety study to set the company up to make A BLA submission…"); ¶ 90 ("NORSE 1 study design was confirmed in our April 2018 FDA meeting to be one of our two adequate and well controlled clinical trials"); ¶ 91 (Company represented that the FDA had accepted the study design of the NORSE 1 and NORSE 2 trials at an April 2018 End-of-Phase 2 meeting.). Thus, Defendants had access to information regarding the adequate clinical trial size required by the FDA.

189. The above is further supported by Defendant Trenary's post-Class Period admission that Defendants were aware of the deficiencies in ONS-BLA submission. On August 30, 2023, Defendant Trenary was asked about the contents of the CRL:

> **Q – Kristen Kluska**: Hi. Good morning, everybody. Also sorry to hear about to this news. Just wanted to ask on some of these items. ***I know that you've had frequent dialogue with them in the past and also withdrew your initial filing to address questions that they have now. First, can you comment if some of the items that were brought up were essentially new, relative to those previous discussions?***
>
> **A – Russ Trenary**: Yes. Thank you, Kristen. I think as we read through that, ***it looked like there were a couple of new things, but a couple of clarifications that FDA was looking for on old items***. And so, I think they're – I think for us, ***the good news was it appeared that everything that they had in there required either a clarification, or some additional information from us***, or some new information from us, because it was a question that had never been received before. So a little bit of a mix there. But I think the – our read as we went through the CMC section was we can handle this.

Thus, the Defendants had knowledge of the BLA's deficiencies from at least May 31, 2022, but omitted to disclose them.

190. Defendant Trenary's admission starkly contrasts his statements regarding confirmations from the FDA that the NORSE 1-3 trials were sufficient to support approval of the ONS-5010 BLA as set forth in Paragraphs 90, 91, 112, 133 and 146.

191. On December 22, 2023, the Company filed a Form 10-K with the SEC. In that filing, the Company revealed that it had lacked a second, appropriately sized, adequate and well-controlled pivotal trial:

> ***We agreed to conduct an additional adequate, and well-controlled clinical trial following discussions with the FDA in support of our BLA for ONS-5010***. In December 2023, we submitted a Special Protocol Assessment, or SPA, to the FDA for this study (NORSE EIGHT) seeking confirmation that, if successful, it will address the FDA's requirement for a second adequate and well-controlled clinical trial to support our planned resubmission of the ONS-5010 BLA. The FDA is expected to respond to the SPA in early February 2024.

192. On January 23, 2024, the Company issued a press release announcing that it had received a SPA for NORSE 8. In that press release, the Company confirmed that NORSE 8 would comply with the parameters set out in the Wet AMD Guidance:

> NORSE EIGHT will be a randomized, controlled, parallel-group, masked, non-inferiority study of ***approximately 400 newly diagnosed***, wet AMD subjects randomized in a 1:1 ratio to receive 1.25 mg ONS-5010 or 0.5 mg ranibizumab intravitreal injections. Subjects will receive injections at Day 0 (randomization), Week 4, and Week 8 visits.

> The primary endpoint will be mean change in BCVA from baseline to week 8. Outlook Therapeutics expects NORSE EIGHT topline results and resubmission of the ONS-5010 BLA by the end of calendar year 2024.

PLAINTIFFS' CLASS ACTION ALLEGATIONS

193. Plaintiffs bring this action as a class action pursuant to Federal Rule of Civil Procedure 23(a) and (b)(3) on behalf of a Class, consisting of all those who purchased or otherwise acquired Outlook securities during the Class Period (the "Class"); and were damaged upon the revelation of the alleged corrective disclosures. Excluded from the Class are Defendants herein, the officers and directors of the Company, at all relevant times, members of their immediate families and their legal representatives, heirs, successors or assigns and any entity in which Defendants have or had a controlling interest.

194. The members of the Class are so numerous that joinder of all members is impracticable. Throughout the Class Period, Outlook securities were actively traded on the NASDAQ, with an average weekly volume of 311,870. While the exact number of Class members is unknown to Plaintiffs at this time and can be ascertained only through appropriate discovery, Plaintiffs believe that there are hundreds or thousands of members in the proposed Class. According to the Company's 2022 Form 10-K, "there were approximately 96 stockholders of record," but the "actual number of stockholders is greater than this number of record holders, and includes stockholders who are beneficial owners, but whose shares are held in

street name by brokers and other nominees." Record owners and other members of the Class may be identified from records maintained by Outlook or its transfer agent and may be notified of the pendency of this action by mail, using the form of notice similar to that customarily used in securities class actions.

195. Plaintiffs' claims are typical of the claims of the members of the Class as all members of the Class are similarly affected by Defendants' wrongful conduct in violation of federal law that is complained of herein.

196. Plaintiffs will fairly and adequately protect the interests of the members of the Class and have retained counsel competent and experienced in class and securities litigation. Plaintiffs have no interests antagonistic to or in conflict with those of the Class, and have retained experienced counsel for the benefit of the Class.

197. Common questions of law and fact exist as to all members of the Class and predominate over any questions solely affecting individual members of the Class. Among the questions of law and fact common to the Class are:

- whether Defendants misrepresented their regulatory communications with the FDA;

  whether Defendants misrepresented the evidence of efficacy submitted to the FDA;

- whether Defendants misrepresented the deficiencies of their selected manufacturing partners, FujiFilm and Ajinimoto;

- whether Defendants' misrepresentations violated the Securities Exchange Act of 1934;

- whether Defendants acted knowingly or recklessly in making these misrepresentations to investors;

- whether the prices of Outlook securities during the Class Period were artificially inflated because of the Defendants' conduct complained of herein; and

- whether Plaintiffs and other members of the Class have sustained damages and, if so, what is the proper measure of damages.

198. A class action is superior to all other available methods for the fair and efficient adjudication of this controversy since joinder of all members is impracticable. Furthermore, as the damages suffered by individual Class members may be relatively small, the expense and burden of individual litigation make it impossible for members of the Class to individually redress the wrongs done to them. There will be no difficulty in the management of this action as a class action.

199. Plaintiffs will rely, in part, upon the presumption of reliance established by the fraud-on-the-market doctrine in that:

- Defendants made public misrepresentations or failed to disclose material facts during the Class Period;

- the omissions and misrepresentations were material;

- Outlook securities are traded in an efficient market;

- the Company's shares were liquid and traded actively during the Class Period;

- the Company traded on the NASDAQ and was covered by multiple analysts;

- the misrepresentations and omissions alleged would tend to induce a reasonable investor to misjudge the value of the Company's securities; and

- Plaintiffs and members of the Class purchased, acquired and/or sold Outlook securities between the time the Defendants failed to disclose or misrepresented material facts and the time the true facts were disclosed, without knowledge of the omitted or misrepresented facts.

200. Based upon the foregoing, Plaintiffs and the members of the Class are entitled to a presumption of reliance upon the integrity of the market.

201. Alternatively, Plaintiffs and the members of the Class are entitled to the presumption of reliance established by the Supreme Court in *Affiliated Ute Citizens of the State of Utah v. United States*, 406 U.S. 128, 92 S. Ct. 2430 (1972), as Defendants omitted material information in their Class Period statements in violation of a duty to disclose such information, as detailed above.

COUNT I

(Violations of Section 10(b) of the Exchange Act and Rule 10b-5 Promulgated Thereunder Against All Defendants)

202. Plaintiffs repeat and re-allege each and every allegation contained above as if fully set forth herein.

203. This Count is asserted against Defendants and is based upon Section 10(b) of the Exchange Act, 15 U.S.C. § 78j(b), and Rule 10b-5 promulgated thereunder by the SEC.

204. During the Class Period, Defendants made as detailed above untrue statements of material facts and omitted to state material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading; and employed devices, schemes and artifices to defraud in connection with the purchase and sale of securities. Such statements were intended to, and, throughout the Class Period, did: (i) deceive the investing public, including Plaintiffs and other Class members, as alleged herein; (ii) artificially inflate and maintain the market price of Outlook securities; and (iii) cause Plaintiffs and other members of the Class to purchase or otherwise acquire Outlook securities and options at artificially inflated prices.

205. By virtue of their access to the actual facts, interactions and positions detailed above, review of other approved drugs, claims to investors that they were knowledgeable about the regulatory process and competitive landscape, participation in and knowledge of confidential regulatory communications with the Company, and inspections of and discussions with their manufacturing partners, Defendants had actual knowledge of the materially false and misleading statements and material omissions alleged herein and intended thereby to deceive Plaintiffs and the other members of the Class, or, in the alternative, Defendants acted with reckless disregard for the truth in that they failed or refused to ascertain and disclose such facts as would reveal the materially false and misleading nature of the statements

made, although such facts were readily available to Defendants. Said acts and omissions of Defendants were committed willfully or with reckless disregard for the truth. In addition, each Defendant knew or recklessly disregarded that material facts were being misrepresented or omitted as described above.

206. Information showing that Defendants acted knowingly or with reckless disregard for the truth is peculiarly within Defendants' knowledge and control. As the senior executives of Outlook directly involved in describing the Company's regulatory progress, clinical progress, and manufacturing partners to investors, the Individual Defendants had knowledge of the actual facts that were omitted and/or misrepresented.

207. The Individual Defendants are liable both directly and indirectly for the wrongs complained of herein. Because of their positions of control and authority, the Individual Defendants were able to and did, directly or indirectly, control the content of the statements of Outlook. As officers and/or directors of a publicly-held company, the Individual Defendants had a duty to disseminate timely, accurate, and truthful information with respect to Outlook's key drug candidate, ONS-5010. As a result of the dissemination of the aforementioned false and misleading reports, releases and public statements, the market price of Outlook securities was artificially inflated throughout the Class Period. In ignorance of the adverse facts concerning Outlook which were concealed by Defendants, Plaintiffs and the other members of

the Class purchased or otherwise acquired Outlook securities at artificially inflated prices and relied upon the price of the securities, the integrity of the market for the securities and/or upon statements disseminated by Defendants, and were damaged thereby.

208. During the Class Period, Outlook securities were traded on an active and efficient market. Plaintiffs and the other members of the Class, relying on the materially false and misleading statements described herein, which the Defendants made, issued or caused to be disseminated, or relying upon the integrity of the market, purchased or otherwise acquired shares of Outlook securities at prices artificially inflated by Defendants' wrongful conduct. Had Plaintiffs and the other members of the Class known the truth, they would not have purchased or otherwise acquired said securities, or would not have purchased or otherwise acquired them at the inflated prices that were paid. At the time of the purchases and/or acquisitions by Plaintiffs and the Class, the true value of Outlook securities was substantially lower than the prices paid by Plaintiffs and the other members of the Class. The market price of Outlook securities declined sharply upon public disclosure of the facts alleged herein to the injury of Plaintiffs and Class members.

209. As a direct and proximate result of Defendants' wrongful conduct, Plaintiffs and the other members of the Class suffered damages in connection with their respective purchases, acquisitions and sales of the Company's securities during

the Class Period, upon the disclosure that the Company had been disseminating misrepresented financial statements to the investing public.

COUNT II

(Violations of Section 20(a) of the Exchange Act Against the Individual Defendants)

210. Plaintiffs repeat and re-allege each and every allegation contained in the foregoing paragraphs as if fully set forth herein.

211. During the Class Period, the Individual Defendants participated in the operation and management of Outlook, a company with only twenty-four full-time employees, and conducted and participated, directly and indirectly, in the conduct of Outlook's business affairs. Because of their senior positions and day-to-day control, they knew the adverse non-public information about Outlook's misstatement of its ONS-5010 BLA submission, the Company's communications with the FDA regarding the ONS-5010 BLA, and the status of the Company's manufacturing partners' facilities.

212. As CEO and CFO of a publicly owned company, the Individual Defendants had a duty to disseminate accurate and truthful information with respect to every aspect of Outlook's ONS-5010 BLA submission, and to correct promptly any public statements issued by Outlook which had become materially false or misleading.

213. Because of their positions of control and authority as senior officers, the Individual Defendants were able to, and did, control the contents of the various reports, investor conferences, press releases and public filings that Outlook disseminated in the marketplace during the Class Period concerning Outlook's ONS-5010 BLA submission. Throughout the Class Period, the Individual Defendants exercised their power and authority to cause Outlook to engage in the wrongful acts complained of herein.

214. Each of the Individual Defendants, therefore, acted as a controlling person of Outlook. By reason of their senior management positions and/or being directors of Outlook, each of the Individual Defendants had the power to direct the actions of, and exercised the same to cause, Outlook to engage in the unlawful acts and conduct complained of herein. Each of the Individual Defendants exercised control over the general operations of Outlook and possessed the power to control the specific activities which comprise the primary violations about which Plaintiffs and the other members of the Class complain.

215. By reason of the above conduct, the Individual Defendants are liable pursuant to Section 20(a) of the Exchange Act for the violations committed by Outlook.

216. Defendant Kenyon reported to Defendant Trenary, either directly or indirectly. As CEO, he had the ability to control Defendant Kenyon's day-to-day

conduct. As a result, Defendant Trenary is also liable pursuant to Section 20(a) of the Exchange Act for the primary violations committed by Kenyon.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs demand judgment against Defendants as follows:

A. Determining that the instant action may be maintained as a class action under Rule 23 of the Federal Rules of Civil Procedure, and certifying Plaintiffs as the Class representatives;

B. Requiring Defendants to pay damages sustained by Plaintiffs and the Class by reason of the acts and transactions alleged herein;

C. Awarding Plaintiffs and the other members of the Class prejudgment and post-judgment interest, as well as their reasonable attorneys' fees, expert fees and other costs; and

D. Awarding such other and further relief as this Court may deem just and proper.

DEMAND FOR TRIAL BY JURY

Plaintiffs hereby demand a trial by jury.

Dated: April 24, 2024

Respectfully submitted,

POMERANTZ LLP

/s/ Thomas H. Przybylowski

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